UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

In re: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	
This Document Relates To: All Direct Purchaser Class Actions	MDL No. 2836 Civil Action No. 18-md-2836-RBS-DEM **REDACTED - Pursuant to Order dated May 21, 2019**

DIRECT PURCHASER PLAINTIFFS' AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Plaintiffs FWK Holdings, LLC, Rochester Drug Cooperative, Inc., and Cesar Castillo, Inc. (collectively, the "direct purchaser plaintiffs") bring this class action, on behalf of themselves and all others similarly situated, against (i) Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC (collectively, "Merck"), (ii) Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (collectively "Glenmark"), and (iii) Par Pharmaceutical, Inc., based on personal knowledge as to themselves and upon information and belief as to all other allegations, and allege as follows.

I. INTRODUCTION

1. *Merck develops Zetia.* In the early 1990s, following its success with statins, Merck sought to identify new compounds that could reduce cholesterol and prevent the buildup of plaques in arteries. Merck turned to a class of drugs first developed forty years earlier: ACAT inhibitors. Merck quickly identified an initial lead compound, SCH48461, and then focused on its metabolites and metabolite-like analogues, including SCH58235 or ezetimibe. Merck used conventional techniques to develop these compounds into pharmaceutical compositions. Merck obtained three patents for these discoveries (one reissued as U.S. Patent No. RE37,721 (the "RE'721 patent")). Ezetimibe became the active ingredient in the blockbuster drug Zetia.

2. *The RE'721 patent is invalid and/or unenforceable.* In 2006, Merck sued Glenmark – the first generic manufacturer to seek FDA approval to market generic Zetia – alleging infringement of the RE'721 patent. Glenmark argued the RE'721 patent was unenforceable for inequitable conduct: Merck intentionally (and deceptively[1]) failed to tell the

[1] Years later, in another suit, a court denied Merck's motion for summary judgment on deceptive intent, and concluded that the generic had presented adequate evidence of Merck's deceptive intent to proceed to trial.

PTO that compounds claimed in the RE'721 patent were inherent metabolites of compounds Merck publicly disclosed years earlier. Merck also withheld references that would have, at minimum, caused the examiner to ask questions about metabolites and inherency. Glenmark also argued that – separate and apart from inequitable conduct – this inherency rendered the RE'721 patent invalid for anticipation. (Merck knew well the dangers of inherency, and later conceded the invalidity of the RE'721 patent.) Had the case resulted in a decision on the ultimate merits, Glenmark would have prevailed.

3. *Glenmark and Par enter into a distribution agreement*. Less than two weeks before Glenmark and Merck were scheduled to go to trial, Glenmark and Par entered into a marketing and distribution agreement making Par the "exclusive distributor" of Glenmark's generic Zetia. Among other things, this agreement provided that Glenmark and Par would share all generic Zetia sales revenues [redacted] nd that Par would have an equal say in "all material decisions" related to the ongoing litigation. It also prohibited Glenmark from entering into any settlement of the Merck-Glenmark patent litigation without Par's express written consent and required Glenmark to pay Par [redacted] of any amount received through any such settlement.

4. *Unlawful reverse payment*. Ten days later and two days before trial, Merck and Glenmark decided to settle with Par's express consent. The Supreme Court holds that resolving patent infringement litigation by having the plaintiff make a large and unjustified payment to the allegedly infringing defendant violates federal antitrust law (assuming the other elements are satisfied). Nevertheless, Merck paid Glenmark and Par to stay out of the market for almost five years. Merck's payment took the form of an agreement not to launch its own generic version of Zetia (called an "authorized generic"). Merck's no-authorized-generic ("no-AG") promise was worth an additional $800 million in sales to Glenmark and Par. Glenmark and Par both

knowingly and voluntarily entered into the unlawful reverse-payment agreement with Merck.

5. *180-day exclusivity.* As first filer, Glenmark earned the right to keep other generic companies off the market for 180 days; this was its statutory reward. But Glenmark could not keep Merck from selling a generic. Brand companies launch authorized generics, particularly during a first filer's so-called 180-day exclusivity period, in an effort to staunch the massive loss of revenue attending generic entry. The brand's authorized generic takes up to 50% of generic sales away from the first filer. So even though they are selling at a lower price point than the brand, authorized generics let the brand hold on to sales that it otherwise would lose.

6. *Earlier generic entry.* In the absence of Merck's large and unjustified payment, Glenmark and Merck would have each launched a generic version of Zetia as early as December 6, 2011 and, in any event, well before December 12, 2016. Additional generics would have launched six months later. The presence of so many generics would have driven prices down to competitive levels.

7. *Damages to the class.* The direct purchaser plaintiffs and the direct purchaser class have been injured by Merck's, Glenmark's, and Par's conduct. In the absence of the unlawful agreement, class members would have been able to buy less-expensive generic ezetimibe instead of branded Zetia from as early as December 6, 2011 through the present. The class has likely paid hundreds of millions in overcharges as a result of Merck's, Glenmark's, and Par's unlawful agreement.

II. PARTIES

8. Plaintiff FWK Holdings, LLC ("FWK") is a limited liability company organized under the laws of the state of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Company, which, during the class period, as defined below, purchased brand Zetia directly from Merck at supracompetitive

prices, and therefore suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

9. Plaintiff Rochester Drug Cooperative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, New York 14624. During the class period, as defined below, RDC purchased Zetia (ezetimibe) directly from defendants, and was injured as a result of defendants' unlawful conduct.

10. Plaintiff Cesar Castillo, Inc. ("Castillo") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located in Rio Piedras, Puerto Rico. During the relevant period, as defined below, Plaintiff purchased brand Zetia directly from Merck at supracompetitive prices, and therefore suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

11. Merck & Company, Inc. is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is or was the parent company of defendants Merck Sharp & Dohme Corporation and MSP Singapore Company LLC.

12. Merck Sharp & Dohme Corporation is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is a subsidiary of Merck & Company, Inc. and the assignee of patents relevant to this lawsuit.

13. Schering-Plough Corporation was a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

14. Schering Corporation was a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It was a wholly owned subsidiary of Schering-Plough Corporation and the original assignee of the relevant patents.

15. In 2009, as part of Merck & Company, Inc.'s acquisition of Schering-Plough Corporation, Merck & Company, Inc. merged into Schering-Plough Corporation. Schering-Plough Corporation subsequently changed its name to Merck & Company, Inc., and the company originally known as Merck & Company, Inc. changed its named to Merck Sharp & Dohme Corporation.

16. MSP Singapore Company LLC ("MSP") is a company organized and existing under the laws of the state of Delaware, with its principal place of business at 200 Galloping Hill Road, Kenilworth, NJ 07033. MSP is a subsidiary of Merck & Company, Inc. and was the exclusive licensee of the relevant patents.

17. Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC are collectively referred to in this complaint as "Merck."

18. Glenmark Pharmaceuticals Limited is a company organized and existing under the laws of India, with its corporate office at Glenmark House, B. D. Sawant Marg, Andheri (E), Mumbai 400 099, India, and its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026, India.

19. Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. It is a wholly owned subsidiary of Glenmark

Pharmaceuticals Limited. From 2002, when Glenmark Pharmaceuticals Inc., USA was incorporated, forward, the company has been referred to as, done business under, and/or formally been known as, both Glenmark Pharmaceuticals Inc., USA and, at points, Glenmark Generics Inc., USA. Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (including when the company was known as Glenmark Generics Inc., USA) are collectively referred to in this complaint as "Glenmark."

20. Par Pharmaceutical, Inc. ("Par") is a New York corporation with its principal place of business in Chestnut Ridge, New York. Par is a subsidiary of Endo International plc, an Irish corporation with its U.S headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par, and combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. As used in this complaint, "Par" encompasses relevant predecessors- and successors-in-interest.

21. All of the defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

III. JURISDICTION AND VENUE

22. This action alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, that are actionable under section 4 of the Clayton Act, 15 U.S.C. § 15(a). The action seeks to recover treble damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiff and members of the class resulting from the following: (i) the

defendants' conspiracy to monopolize and to restrain trade in the United States market for Zetia and its generic equivalents.

23. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1337(a) (antitrust), and 15 U.S.C. § 15 (Clayton Act).

24. Venue is appropriate within this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) (general venue provision). The defendants transact business within this district, and the defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district. Further, the defendants and/or their agents may be found in this district.

25. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

A. The regulatory structure for approval and substitution of generic drugs.

26. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[2] manufacturers that create a new drug must obtain approval from the Food and Drug Administration ("FDA") to sell the product by filing a New Drug Application ("NDA").[3] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable

[2] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 et seq.).

[3] 21 U.S.C. §§ 301-392.

patents.[4]

27. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.[5] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[6]

28. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman amendments

29. The Hatch-Waxman amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[7] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the

[4] 21 U.S.C. § 355(a), (b).

[5] For example, patents covering processes for making drug products may not be listed in the Orange Book.

[6] 21 U.S.C. § 355(b)(1), (c)(2).

[7] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an "AB" rating.

30. The FDCA and Hatch-Waxman amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.[8]

31. Through the Hatch-Waxman amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

32. The Hatch-Waxman amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[9] Generics are dispensed about 95% of the time when a generic form is

[8] 21 U.S.C. § 355(j)(8)(B).

[9] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014).

available.[10]

2. Regulatory exclusivities for new drugs.

33. In order to promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provided for exclusivities (or exclusive marketing rights) for new drugs. These exclusivities are granted by the FDA upon approval of a drug if statutory requirements are met. These exclusivities are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

34. One such exclusivity, New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[11]

35. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[12]

36. Regulatory exclusivities are not always absolute bars to generic entry. For

[10] *Id.* at 51.

[11] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[12] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

example, some can be overcome by carving out information in the label or for other reasons.[13]

3. ANDA paragraph IV certifications.

37. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a "paragraph I certification");

b. That the patent for the brand has expired (a "paragraph II certification");

c. That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or

d. That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[14]

38. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA.[15] Until one of those conditions occurs, the FDA may grant

[13] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

[14] 21 U.S.C. § 355(j)(2)(A)(vii).

[15] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

"tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA is ready for final approval but for the 30-month stay.

4. The first filer's 180-day exclusivity period.

39. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

40. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman amendments grant the first paragraph IV generic manufacturer ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[16] That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days.[17]

41. The 180-day window is often referred to as the first filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer, because a brand manufacturer (such as Merck) can launch an authorized generic ("AG") at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose.

[16] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[17] Or, until its first-filer exclusivity has been forfeited. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA. There is no forfeiture here.

42. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first filer.[18]

43. A first filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

5. Patents are not bulletproof.

44. Patents are not bulletproof. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the PTO, by court decision, or by jury verdict. A patent holder at all times bears the burden of proving infringement.

45. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

46. A patent is invalid or unenforceable when the disclosed invention is obvious in light of earlier prior art.

47. A patent is also invalid or unenforceable when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution.

48. A patent is also invalid or unenforceable when a later acquired patent is not

[18] *FTC v. Actavis, Inc.*, 570 U.S. __, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

49. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

50. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.[19] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[20]

B. The competitive effects of AB-rated generic competition.

51. Generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is their price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition

[19] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

[20] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

between a branded product and its generic version, or between generic versions, is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor. This discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers, especially direct purchasers.

52. Since the passage of the Hatch-Waxman amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.[21] As a result, competition from generics is viewed by brand manufacturers, such as Merck, as a grave threat to their bottom lines.

53. Generic competition enables all direct purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced

[21] *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

price.

54. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue to profitably charge supracompetitive prices. Brand manufacturers, such as Merck, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means – to delay or prevent generic competition.

1. The first AB-rated generic is priced below the brand.

55. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[22] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

56. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

[22] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

2. Later generics drive prices down further.

57. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[23]

58. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

59. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months.[24] (This percentage erosion of brand sales holds regardless of the number of generic entrants.) In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[25]

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[23] *See, e.g.*, Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 Int'l J. Indus. Org. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & Econ. 311 (2000).

[24] FTC 2011 AG Study at 66-67.

[25] *See Generic Drugs: Questions and Answers*, FDA, http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last visited Jan. 11, 2018).

3. Authorized generics, like other generics, compete on price.

60. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand product in a different package.

61. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[26]

62. Brand manufacturers sometimes begin selling AGs before the first-filer generic enters the market in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

63. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period). A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[27]

64. The FTC found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[28] The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales

[26] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[27] Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 790, 796 (2007).

[28] FTC 2011 AG Study at 139.

away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

65. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic's 180-day exclusivity period. All drug industry participants recognize this. PhRma recognizes it.[29] Generic companies recognize it.[30] So do brand companies.[31]

C. Pharmaceutical manufacturers game the regulatory structure in order to impair competition.

66. When they do not face generic competition, brand manufacturers can usually sell the brand far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit

[29] Brand industry group PhRma sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

[30] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic quantified the fiscal consequences of competing with an authorized generic version of the brand drug Paxil, determining that the authorized generic reduced its first generic's revenues by *two-thirds*, or by approximately *$400 million*. Comment of Apotex Corp. in Support of Mylan Citizen Petition (Mar. 24, 2004), http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P=0075-emc00001.pdf. In 2004, generic company Teva acknowledged that an authorized generic would "severely devalu[e]" its 180 exclusivity because an authorized generic "effectively transfers much of the profit value from the generic challenger [to the authorized generic]" and "allows the [authorized generic] to seize a significant share of the generic supply chain." Teva Citizen Petition, Docket No. 2004P-0261/CPI (June 9, 2004), www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf.

[31] Commenting on Teva's FDA petition, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a *flagrant effort to stifle price competition* – to Teva's benefit and the public's detriment." Comment of Pfizer at 7, Docket No. 2004P-0261 (June 23, 2004), http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/062904.htm#04P0261; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf.

margins is what economists call market power. When generics enter the market, however, they quickly take 80% or more of the unit sales. And when multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production. This competition puts an end to the brand manufacturer's market power and delivers enormous savings to drug purchasers.

67. Brand and first-filer generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

68. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales.

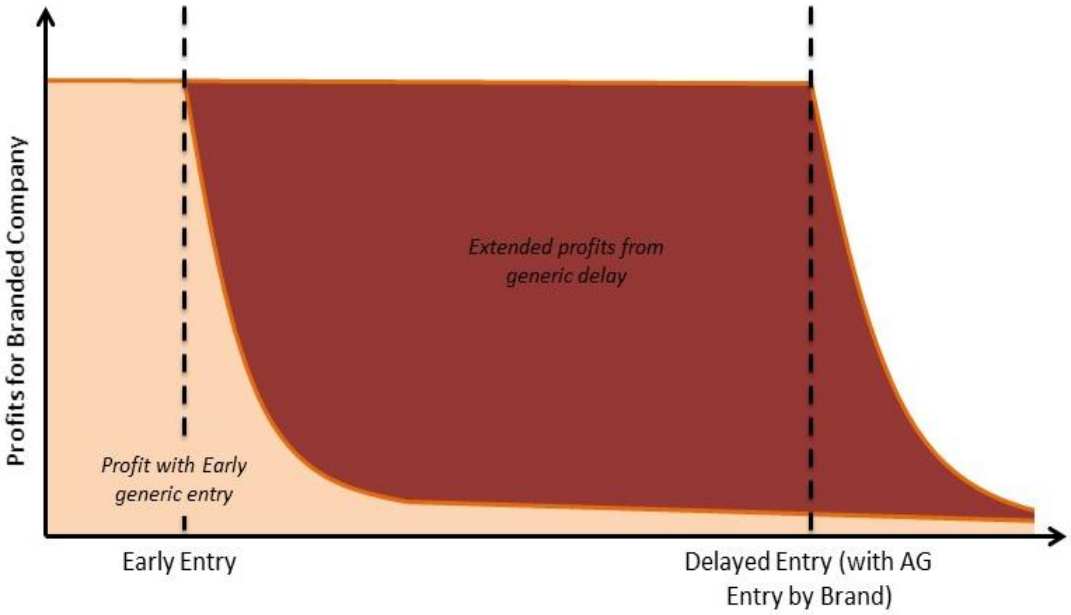
69. When generic entry occurs, the brand manufacturer loses most of the unit sales; generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

70. To prevent this from happening, brand and generic manufacturers sometimes – unlawfully – agree to not compete and instead split the purchaser savings between themselves.

71. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the

latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (i.e., while the litigation is still pending) or prevails in the patent litigation and then launches its product.

Figure 1. Impact of Generic Delay on Brand Profits



72. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains through some means. Pay-offs from the brand manufacturer are the means by which brand and generic manufacturers divide between themselves the ill-gotten gains that delayed competition makes possible. These unlawful pay-off deals are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

73. The brand manufacturer may choose to – unlawfully – pay off only the first filer, even if other generic manufacturers are also lined up to challenge the patents. The first filer's

agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products.

74. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

75. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

76. When an anticompetitive agreement with the first filer is already in place, however, pursuing the litigation to conclusion becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement). The later generics have to bear the brunt of the litigation costs themselves and, upon prevailing in the patent litigation, expect to face competition from at least the first-filer generic, and typically an authorized generic as well, despite having expended time and resources litigating the infringement case. The first settlement between a brand and first-filer generic (such as the Glenmark agreement at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first filer, the first filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

77. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

78. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. No-AG clauses provide a means for manufacturers to share the gains from conspiring.

79. In the 1990s, the pay-offs from brand manufacturers often took the form of cash payments to the generic competitor. Since the 2000s, as a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to hide pay-offs.

80. One form of pay-off, at issue here, is a no-AG promise. With a no-AG promise, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters.

81. Again, the first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its AG under the authority of its NDA. The Hatch-Waxman amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

82. Absent a no-AG promise, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace. But competition from an AG has a drastically negative effect on the first-filer generic's revenues. Competition from an AG typically cuts the first filer's

revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower – delivering commensurate savings to drug purchasers.

83. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by not competing with an AG. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition for the first 180 days of marketing. But drug purchasers lose.

84. The brand and first filer's reciprocal pledges not to compete harm purchasers thrice over. The pact delays the first filer's entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. By delaying the first filer's entry, the pact also delays the time when other, later, generics enter. And the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period, particularly price competition that would otherwise occur between the first filer's generic and the brand's AG.

85. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I

> launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[32]

Courts agree that no-AG agreements are a form of payment actionable under *Actavis* and are anticompetitive.[33]

86. For a first ANDA filer (like Glenmark) for a brand drug with billions of dollars in annual sales (like Zetia), the difference between selling a generic without having to compete against an AG and selling in competition with an AG can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

87. Figure 2 depicts what happens when a settlement agreement includes a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic).

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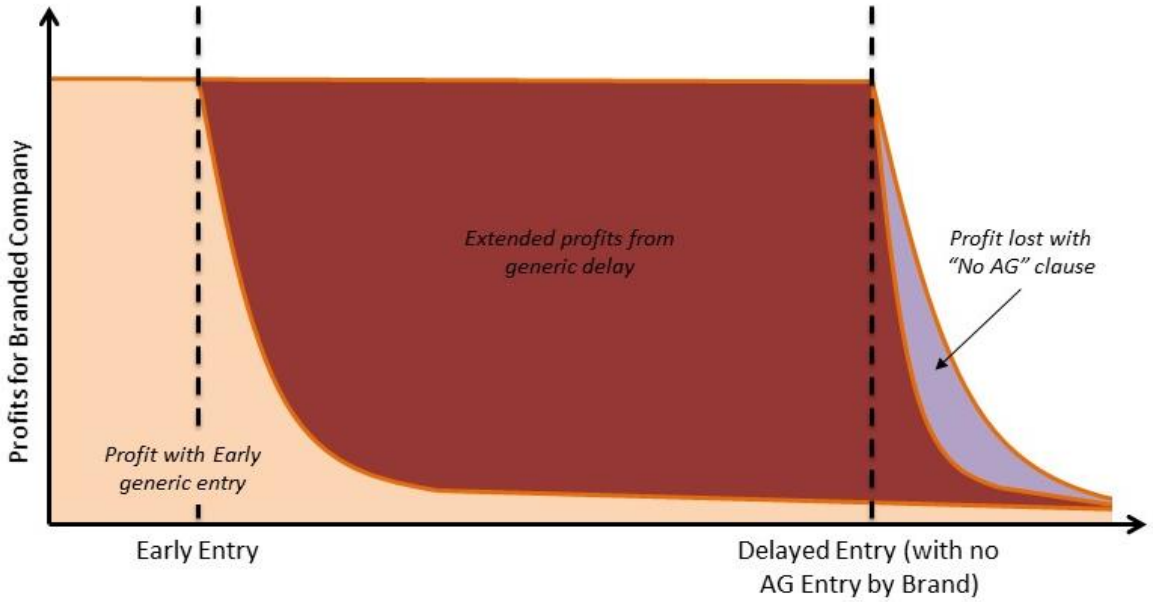
[32] Press Release, FTC, Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics, (June 24, 2009), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf.

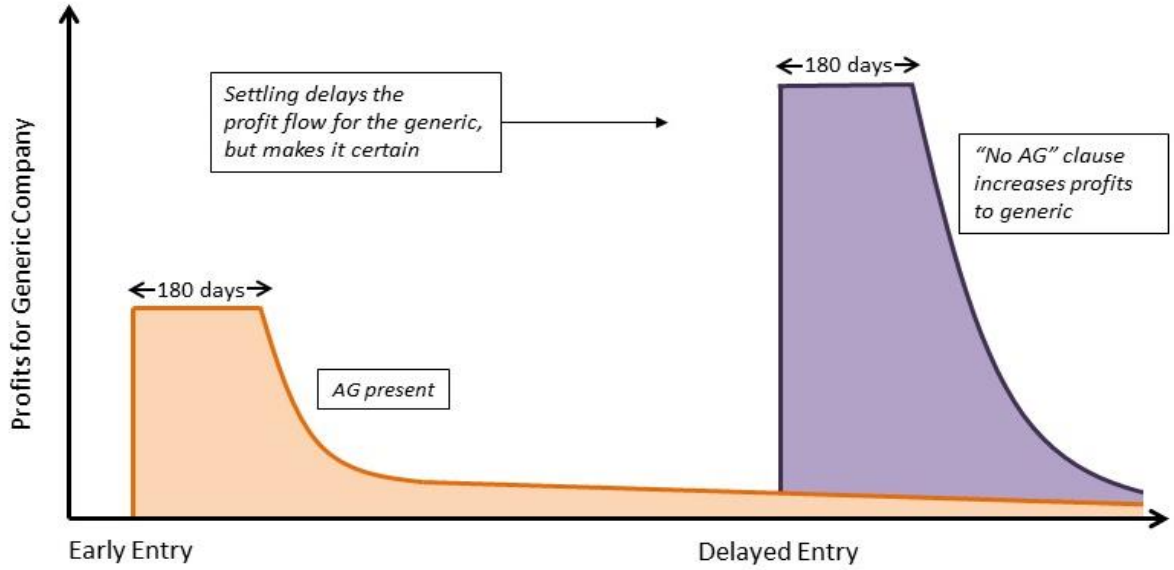
[33] *See In re Loestrin 24 Fe Antitrust Litig*., Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *25-26 (1st Cir. Feb. 22, 2016); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *23-25 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig*., No. 11-cv-5479, 2014 U.S. Dist. LEXIS 142206, at *62 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig*., 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig*., 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

Figure 2. Impact of No-AG Clause on Brand Profits



88. Figure 3 depicts the generic manufacturer's principal considerations in deciding whether to accept a settlement that includes a no-AG promise. Without a settlement, the generic could enter earlier – either when the 30 month stay expires ("at risk") or when it wins the litigation. The generic manufacturer's profits (gross margins) would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (i) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent and (ii) it is expected that the brand manufacturer will launch an authorized generic. With a no-AG promise, the profit flow occurs later but is more certain and is larger – roughly twice the size – because the generic manufacturer does not lose half of the market to the brand manufacturer's authorized generic and can charge a higher price.

Figure 3. Impact of No-AG Promise on Generic's Profits



89. Pay-offs by means of no-AG clauses usually exceed the value that the first filer could have obtained *even if it had won* the patent infringement litigation. By settling the patent case in exchange for a no-AG payoff, the first filer converts that critical six months into a period of total generic exclusivity that it was not otherwise entitled to, thus doubling its unit sales and making those sales at a higher price.

V. FACTS

A. A short primer on cholesterol-lowering drugs.[34]

90. Cholesterol is essential in constructing and maintaining membranes in animal cells. It makes up part of the myelin sheath that insulates nerve cells and facilitates conducting nerve impulses. It is also an important precursor for making vitamin D and steroid hormones in

[34] *See, e.g.*, C. Robin Ganellin, *Discovery of the Cholesterol Absorption Inhibitor, Ezetimibe, in* C. Robin Ganellin, Stanley Roberts & Roy Jefferis, *Introduction to Biological and Small Molecule Drug Research and Development* (2013) (reviewed by Dr. Stuart B. Rosenblum, one of the inventors of ezetimibe).

the body.

91. Our bodies derive cholesterol from two sources. We make cholesterol, mostly in our livers. Our bodies also absorb cholesterol through our intestines. This absorption includes both cholesterol from the foods we eat and the cholesterol we make. About 50% of the cholesterol made in our livers is reabsorbed through our intestines.

92. Common thinking is that high cholesterol is associated with coronary heart disease and atherosclerosis in some populations. Atherosclerotic coronary heart disease is a major cause of death and cardiovascular morbidity in the western world.

93. In the 1950s, scientists developed several drugs thought to lower cholesterol levels.

94. In 1953, scientists in France reported that phylacetic acid and its analogues – fibrates – lowered cholesterol levels. This discovery led to the approval of ethyl ester clofibrate in the U.S. in 1967; it was later found to have unacceptable side effects and was replaced with other fibrates.[35]

95. In the 1970s and 80s, scientists discovered a group of cholesterol-lowering drugs known as statins. Statins lower cholesterol levels by inhibiting the enzyme that regulates the production of cholesterol in the liver, HMG-CoA reductase. In 1987, Merck launched the first statin: lovastatin. Merck later launched a second statin: simvastatin. Other drug companies – including Sankyo, Novartis, Pfizer, and AstraZeneca – followed suit. Statins, as a class, were for many years the most profitable drugs in pharmaceutical history.

96. The 1990s saw a renewed interest in fibrates as (1) cholesterol lowering drugs had

[35] In the 1980s, scientists discovered that fibrates worked by interacting with the peroxiosome proliferator-activated receptors (PPAR-α) in the liver, muscle, and other tissues.

become big business, (2) their mechanism of action became better understood, and (3) clinical trials demonstrated the efficacy of fibrates on cardiovascular events. Scientists had discovered that fibrates inhibited the enzyme Acyl-CoA cholesterol acyltransferase (ACAT), which blocked the absorption of cholesterol in the intestine (and may also inhibit cholesterol deposited within vascular walls). And clinical data showed that fibrates worked. So while statins had become first line treatments, fibrates were still widely prescribed.

B. Early 1990s: Merck develops hydroxyl-substituted azetidinone compounds useful as hypocholesterolemic agents.

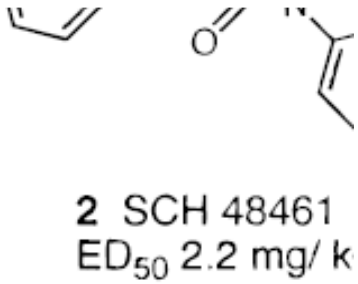
97. In the early 1990s, Merck embarked on a broad chemical program to discover novel ACAT inhibitors. Scientists working in Schering's New Jersey facilities began developing azetidinone compounds that, hopefully, would be useful in reducing cholesterol levels in humans. Those scientists included Stuart B. Rosenblum, Sundeep Dugar, Duane A. Burnett, John W. Clader, and Brian McKittrick.

98. In lab experiments conducted over a couple of years or less, these scientists identified a lead compound, SCH48461, and inherent metabolites and metabolite-like analogues of that compound, including SCH58235 or "ezetimibe." (Ezetimibe would eventually become the active ingredient in Zetia).

99. SCH 48461 is (3R,3S)-1,4-bis-(4-methoxyphenyl)-3-(3-phenylpropyl)-2-azetidinone.[36] It is pictured in Figure 4 below. The negative enantiomer possesses significantly greater *in vivo* activity.

[36] *See* Brian G. Salisbury, *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption, SCH 48461*, 115 Atherosclerosis 45 (1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

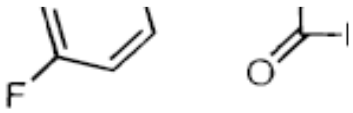
Figure 4. SCH 48461



100. SCH 58235 is 1-(4-fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3s)-hydroxypropyl]-(4S)-(4-hydroxypheyl)-2-azetidinone.[37] The use of halogen to block sites of metabolism was then well known. To create SCH 58235, Merck scientists used routine laboratory techniques to add fluorine to the two phenyl rings, in order to lessen the likelihood of hydroxylation (and thereby keep the compound in the body longer). It is pictured in Figure 5 below.

[37] Stuart B. Rosenblum, *Discovery of 1-(4-Fluorophenyl)-(3*R*)-[3-(4-fluorophenyl)-(3*S*)-hydroxypropyl]-(4*S*)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998).

Figure 5. SCH 58235, Ezetimibe



1 SCH 582
ED_{50} 0.04 n

101. Upon discovering these and other useful compounds (and their metabolites), and recognizing their potential to be developed into lucrative prescription drugs down the road, Merck set out to obtain broad patent protection.

102. Merck knew that publishing journal articles about its research and development could potentially undermine its ability to patent its inventions. So while its discoveries occurred in the early 1990s, its scientists did not publish their discoveries until after the first patent application was filed and, in some instances, only wrote about the development process over a decade later.[38]

[38] *See* John W. Clader, *Ezetimibe and other Azetidinone Cholesterol Absorption Inhibitors*, 5 Current Topics Med. Chem. 243 (2005); John W. Clader, *The Discovery of Ezetimibe: A View from Outside the Receptor*, 47 J. Med. Chem. 1 (2004); Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998); Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997); Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271 (1996); John W. Clader et

C. 1993-1998: Merck applies for, and obtains, the original azetidinone patents (the '365, '115, and '966 patents).

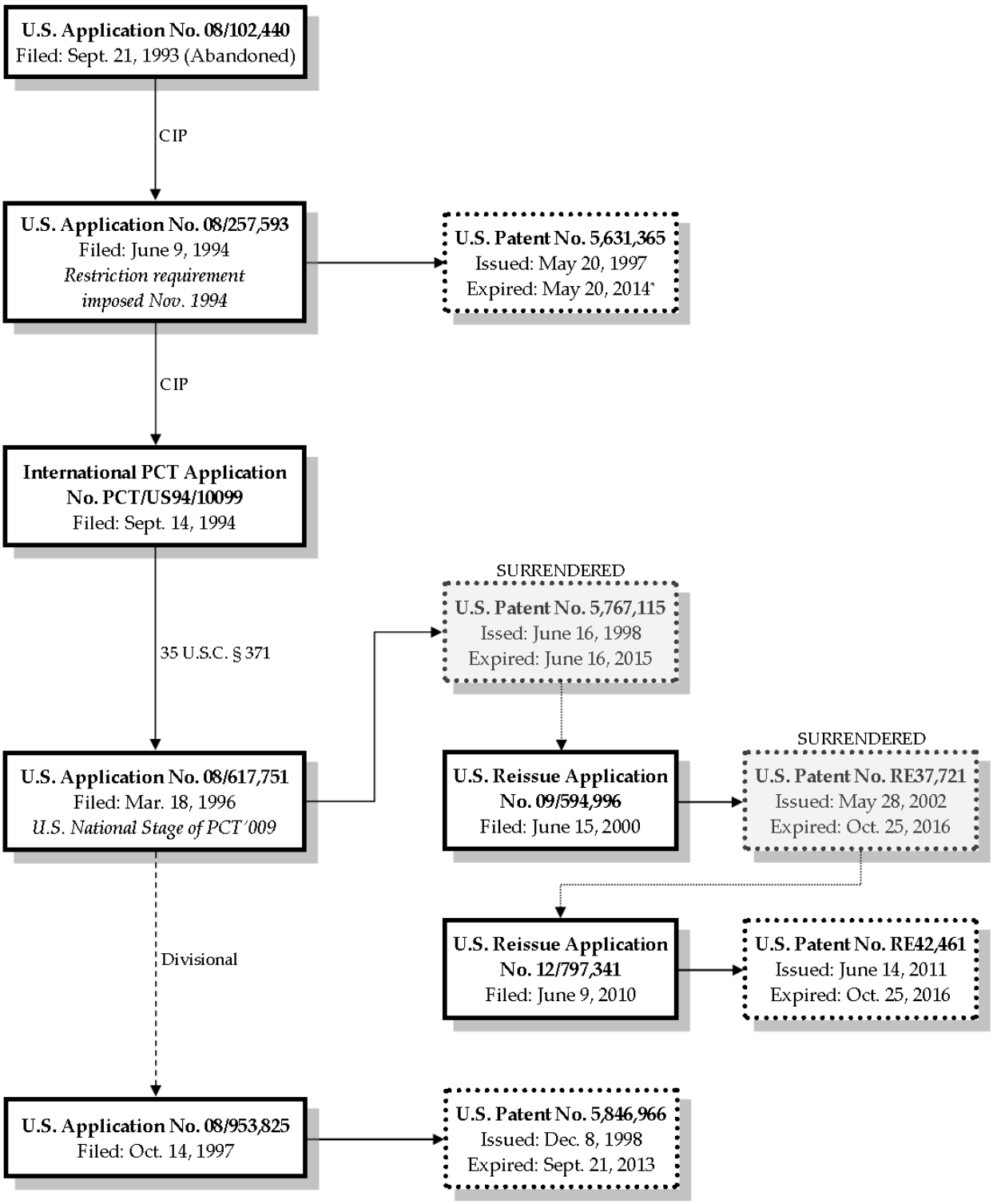
103. Beginning in 1993, Merck filed a series of related U.S. patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents.[39] Three issued as patents; one of these then *re*issued twice.

104. For shorthand, we refer to the family of patents resulting from Merck's efforts here as "the azetidinone patents." All told, the azetidinone patents include the '365 patent, the '115 patent, the '966 patent, the RE'721 patent, and the RE'461 patent.

al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996); Brian A. McKittrick et al., *Stereoselective Synthesis and Biological Activity of* Cis *Azetidinones as Cholesterol Absorption Inhibitors*, 16 *Bioorganic & Med. Chem. Letters* 1947 (1996); Brian G. Salisbury et al., *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption, SCH 48461*, 115 Atherosclerosis 45 (1995); Sundeep Dugar et al., *Gamma-Lactams and Related Compounds as Cholesterol Absorption Inhibitors: Homologs of the β-Lactam Cholesterol Absorption Inhibitor SCH 48461*, 24 Bioorganic & Med. Chem. Letters 2947 (1995); Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

[39] All of the patent applications and communications with the PTO described herein were done by Schering Corporation and its agents, unless otherwise noted.

Figure 6. The Azetidinone Patents



*All expiration dates are calculated without pediatric exclusivity extensions.

1. 1993-1994: Merck files two patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents.

105. On September 21, 1993, Merck filed U.S. Patent Application 102,440, entitled "Hydroxy-Substituted Azetidinone Compounds Useful As Hypocholesterolemic Agents." Merck abandoned the application.

106. On June 9, 1994, Merck filed U.S. Patent Application 257,593 as a continuation-in-part of the abandoned '440 application.

107. Both the '440 application and the '593 application disclosed that the inventions described were useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis – the hardening and narrowing of the arteries due to build-up of fats and cholesterol on artery walls. These applications explained that the liver is the major organ responsible for cholesterol biosynthesis and is the prime determinant of plasma cholesterol levels. When intestinal cholesterol absorption is reduced, less cholesterol is delivered to the liver, which makes less hepatic lipoprotein and clears more plasma cholesterol (mostly LDL). As Merck put it, "the net effect of inhibiting intestinal cholesterol absorption is a decrease in plasma cholesterol levels."

108. Merck went on to prosecute the '593 application for about three years.

2. 1994-1996: Merck files a third and fourth patent application addressing hydroxyl-substituted azetidinone compounds.

109. On September 14, 1994, Merck filed the PCT/US94/10099 application as a continuation-in-part of the '593 application. The PCT'099 application added two example compounds in the specification, 3L and 3M, as well as *in vivo* data for 3L, 3M, and 6A-1.

110. On March 18, 1996, the PCT'0099 application entered the national stage in the United States under 35 U.S.C. § 337 as U.S. Patent Application No. 617,751. The specification

for the ’751 application, as filed, was identical to the specification of the PCT’0099 application.

111. Merck went on to prosecute the ’751 application for a little over two years.

3. Early 1997: Merck obtains its first azetidinone patent, covering processes (the ’365 patent).

112. On May 20, 1997, the ’593 application – Merck’s second azetidinone patent application – issued as U.S. Patent No. 5,631,365. The ’365 patent was the first-issued Merck azetidinone patent.

113. The inventors of the ’365 patent are Drs. Rosenblum, Dugar, Burnett, Clader, and McKittrick. All worked for Schering in New Jersey.

114. The ’365 patent was originally assigned to Schering Corporation of Kenilworth, N.J. In 2012, Merck Sharp & Dohme became the assignee of the ’365 patent by means of a conveyance from Schering Corporation.

115. The ’365 patent states that “the present invention relates to hydroxyl-substituted azetidinones useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis . . . the invention also related to a process for preparing hydroxyl-substituted azetidinones.” It observes that “A few azetidinones have been reported as being useful in lowering cholesterol and/or in inhibiting the formation of cholesterol-containing lesions in mammalian arterial walls,” citing U.S. Patent No. 4,983,594; Ran, *Indian J. Chem.* (1990); European Patent Publication No. 264,231; European Patent No. 199,630; and European Patent Application No. 337,549.

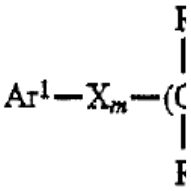
116. The summary of the invention describes hypocholesterolemic compounds of formula I (Figure 6) or a pharmaceutically acceptable salt of those compounds. It also states that the invention “relates to” all of the following:

- “[A] method of lowering the serum cholesterol level in a mammal in need of such treatment comprising administering an effective amount of a

compound of formula I,"

- "[A] pharmaceutical composition comprising a serum cholesterol-lowering effective amount of a compounds of formula I in a pharmaceutically acceptable carrier;"
- "[T]he use of a hydroxyl-substituted azetidinone cholesterol absorption inhibitor of formula I for combined use with a cholesterol biosynthesis inhibitors [e.g., statins] … to treat or prevent atherosclerosis or to reduce plasma cholesterol levels;" and
- "[A] process for preparing certain compounds of formula I comprising [five specific steps]."

Figure 7. Hypocholesterolemic Compounds of Formula I



117. The specification confirms that the invention includes both enantiomers and racemic mixtures, and that one enantiomer may lead to greater cholesterol inhibition than another: "all isomers, including enantiomers . . . are contemplated as being part of this invention . . . including racemic mixtures." "Isomers can be prepared using conventional techniques, either by reacting chiral starting materials or by separating isomers of a compounds of formula I." "Those skilled in the art will appreciate that for some compounds of formula I, one isomer will show greater pharmacological activity than another isomer."

118. The specification notes that compounds of the invention can exist in "pharmaceutically acceptable" salt forms, identifies at least two dozen salt forms, and describes how to prepare salt forms.

119. The specification notes that "Compounds of formula I can be prepared by known methods, for example those described below and in WO93/02048," and then describes several methods of preparation. It then discloses that many, if not all, of the "starting compounds" used are "either commercially available or well known in the art and can be prepared via known methods."

120. The specification notes "We have found that the compounds of this invention lower serum lipid levels, in particular serum cholesterol levels. Compounds of this invention have been found to inhibit the intestinal absorption of cholesterol and to significantly reduce the formation of liver cholesteryl (sic) esters in animal models. Thus, compounds of this invention are hypocholesterolemic agents by virtue of their ability to inhibit the intestinal absorption and/or esterification of cholesterol; they are, therefore, useful in the treatment and prevention of atherosclerosis in mammals; in particular in humans." It goes on to describe the procedure used to determine the in vivo activity of the compounds of formula I, using the "hyperlipidemic Hamster."

121. The '365 patent has four claims. All four claims claim a process of preparing a compound of formula I. Claims 1 and 3 are independent claims; Claims 2 and 4 depend on claims 1 and 3, respectively.

122. The '365 patent expired on May 20, 2014.

4. Late 1997: Merck files a fifth patent application addressing azetidinones, this one addressing combination use with statins.

123. On October 14, 1997, Merck filed U.S. Patent Application 953,825 – titled "combinations of hydroxyl-substituted azetidinone compounds and HMG CoA reductase inhibitors" – as a continuation-in-part of the '751 application.

5. Mid-1998: Merck obtains a second azetidinone patent covering compounds, a composition, and a method of treating atherosclerosis (the '115 patent).

124. On June 16, 1998, the '751 application issued as U.S. Patent No. 5,767,115. The '115 patent had nine claims. Claims 1-7 claim compounds, claim 8 claims a pharmaceutical composition for the treatment or prevention of atherosclerosis (or for the reduction of plasma cholesterol levels), and claim 9 covers a method of treating or preventing atherosclerosis (or reducing plasma cholesterol levels) comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.

125. Ezetimibe (the active ingredient in Zetia) is within the scope of claims 1-3, 5, and 7 of the '115 patent. Ezetimibe is designated "6A" and is described in Example 6 at column 31, lines 1-10 of the specification and in claim 7 at column 40, lines 19-21.

126. According to Merck, the '115 patent expired on June 16, 2015.

6. Late 1998: Merck obtains a third azetidinone patent for use in combination with statins (the '966 patent).

127. On December 9, 1998, the '825 application issued as U.S. Patent No. 5,846,966.

128. All claims in the '966 patent refer to a hydroxyl-substituted azetidinone used *in combination with* an HMG CoA reductase inhibitor – i.e., a statin. Claim 1 refers to hydroxyl-substituted azetidinone compounds used in combination, claims 2-5 refer to compositions of those compounds used in combination, and claim 6 refers to methods of treating or preventing atherosclerosis or reducing plasma cholesterol levels in combination with statins. Claim 8 explicitly refers to simvastatin (the active ingredient in Merck's Zocor) and atorvastatin (Pfizer's Lipitor).

D. 2000: Merck asks the PTO to reissue the '115 patent with new ezetimibe claims.

129. In early 2000, Merck – including Schering Corporation – was preparing a New Drug Application for the drug product that came to be known as Zetia. Merck closely reviewed

the existing patent portfolio, knowing, as all sophisticated pharmaceutical manufacturers do, that the FDA would require them to identify the patents that claim the Zetia product (or a method of using it) by listing them in the Orange Book.

130. On June 15, 2000, Merck filed Reissue Application No. 09/594,996, asking the PTO to reissue the '115 patent. In preliminary remarks, Merck stated that the reissue application was filed "to correct an error concerning the failure to appreciate the full scope of the invention by not including claims of narrower scope directed to one of the most preferred compounds disclosed in the specification," namely, ezetimibe (described as 1-(4-fluoro[phenyl)-3(R)-[3(S)-(4 fluorophenyl)-3-hydroxypropyl)]-4(S)-(4-hydroxyphenyl)-2-azetidinone). Merck proposed adding claims 10-13, claiming the ezetimibe compound (in both prose and graphic form, claims 10 and 11), a pharmaceutical composition for the treatment or prevention of atherosclerosis or the reduction of plasma cholesterol levels (claim 12), a method of treating or preventing atherosclerosis or reducing plasma cholesterol levels (claim 13), and a method of use thereof.

131. Merck submitted a declaration in support of reissue signed by James R. Nelson, Staff Vice President and Associate General Counsel, Patents & Trademarks at Schering-Plough Corporation and Vice President at Schering Corporation. Nelson described the error as "the failure to include a specific claim to one of the most preferred compounds."

E. 2001-2002: Merck obtains approval for Zetia, the RE'721 patent, and a corresponding 16-month patent term extension.

1. 2001: Merck files an NDA for Zetia.

132. On December 27, 2001, while the application for reissue was pending, Merck submitted NDA 21445 seeking FDA approval to market ezetimibe tablets in the United States under the brand name Zetia for the treatment of hypercholesterolemia.

133. The NDA sponsor is sometimes identified as Merck/Schering-Plough

Pharmaceuticals and sometimes identified as MSP Singapore Company LLC. The proposed labeling submitted with the NDA is marked "COPYRIGHT Merck/Schering-Plough Pharmaceuticals." In correspondence, Schering Corporation is identified as the U.S. agent for MSP Singapore. During its review, the FDA corresponded with Schering's Regulatory Affairs department, including with Joseph F. Lamendola, Jack Scannelli, and Beth DiDomenico.

134. The FDA's review of Zetia took about ten months. Merck later sought and obtained a patent term extension for the period of time encompassed by this regulatory review (discussed below).

2. 2002: The PTO reissues the '115 patent as the RE'721 patent.

135. On May 28, 2002, the RE'966 application issued as U.S. Patent No. RE37,721 with new claims 10-13. These included the compound ezetimibe (claims 10-11), a composition of ezetimibe (claim 12), and a method of using ezetimibe to treat or prevent atherosclerosis or reduce plasma cholesterol levels (claims 13).

3. 2002: The FDA approves Zetia.

136. On October 25, 2002, the FDA approved the Zetia NDA and granted it a five-year New Chemical Entity exclusivity. Merck launched Zetia later that month. Zetia quickly became a steady source of profits for Merck, with annual U.S. sales of about $1 billion in 2010, $1.4 billion in 2014, and $2.6 billion by 2016.

137. The originally approved labeling reflects that Zetia is manufactured for Merck/Schering-Plough Pharmaceuticals by Schering Corporation *or* Merck & Co., Inc.

4. 2002: Merck seeks a 16-month patent term extension for the RE'721 patent.

138. On December 12, 2002, Merck – via James R. Nelson of Schering – requested an extension of the patent term of the RE'721 patent based on the duration of the FDA's review of the Zetia NDA (pursuant to 35 U.S.C. § 156 and 37 C.F.R. §§ 1.710-1.791). Merck asked that an

additional 497 days of patent term be added.

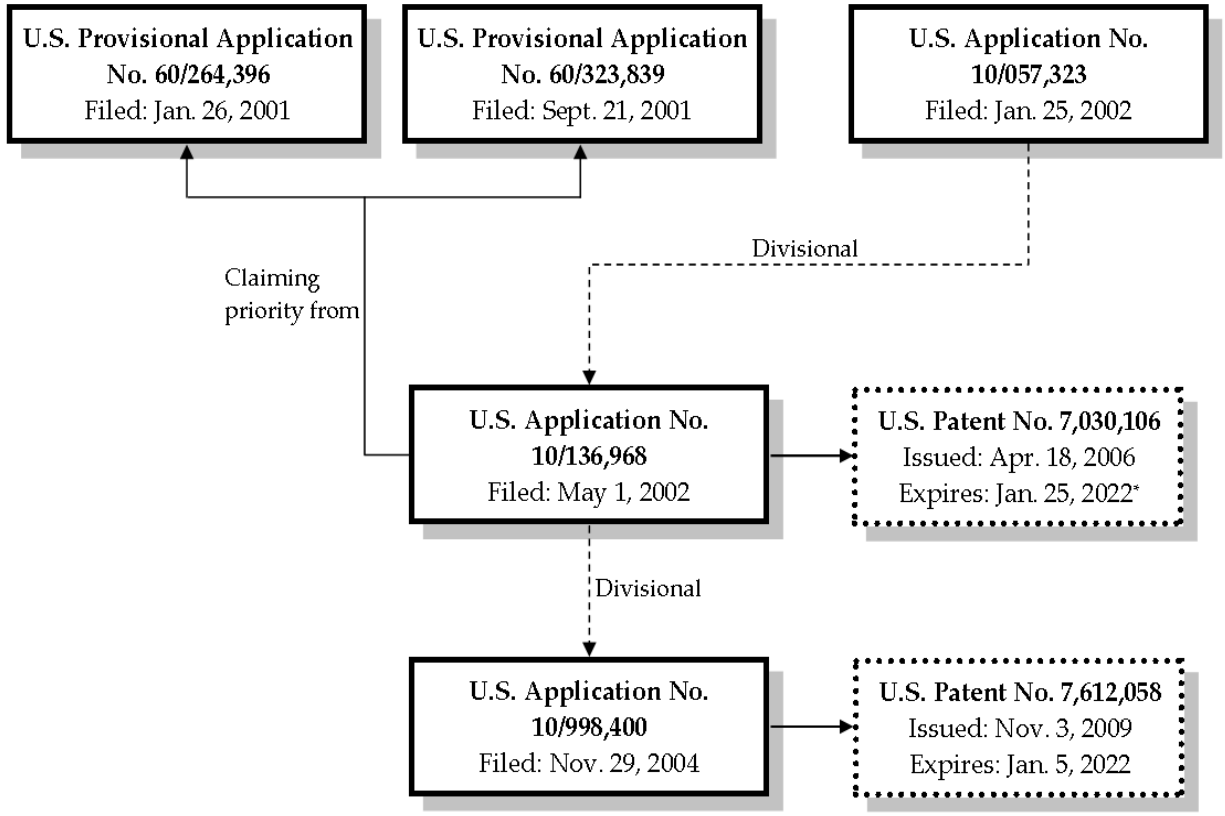
139. Ultimately, on January 17, 2006, the RE'721 patent was extended through October 25, 2016. The PTO (in reliance on information obtained from Schering and confirmed by the FDA) determined that the RE'721 patent was eligible for a patent term extension of 497 days. The PTO noted that the period of FDA review was 948 days, but noted that the 14-year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension: "the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years." With the extension, grant in 2006, the RE'721 patent was set to expire on October 25, 2016.

F. 2006: Merck obtains its first "sterol non-absorption" patent (the '106 patent).

140. After Merck filed its NDA, but before it was approved, Merck sought to extend its patent protection for Zetia. Merck filed a series of patent applications relating to compounds that inhibit sterol absorption and methods for treating specific conditions with those compounds. Two issued as patents (the '106 patent and the '058 patent). For shorthand, we refer to this family of patents as "the sterol non-absorption" applications and patents.

141. The sterol non-absorption applications did not claim priority to, or derive from, the azetidinone applications. Nor did they share any inventors.

Figure 8. The Sterol Non-Absorption Patents



*All expiration dates are calculated without pediatric exclusivity extensions.

142. On April 18, 2006, Merck's Application No. 10/136,968[40] issued as U.S. Patent No. 7,030,106. The '106 patent was Merck's first sterol non-absorption patent. It has two claims. The inventor is Wing-Kee Philip Cho of Princeton, NJ. The assignee was originally Schering Corporation.

[40] On January 25, 2002, Merck filed Utility Application No. 10/057,323. The '323 application claimed priority to two provisional applications, filed in January 26, 2001 and September 21, 2001, respectively. It did not claim priority to, nor was it related to, the azetidinone patents described above. On May 1, 2002, Merck filed Application No. 10/136,968 as a divisional of the '323 application. The primary examiner was San-Ming Hui. The '323 and '968 applications purported to address compounds and compositions that inhibited sterol absorption.

143. According to Merck, the '106 patent originally was set to expire on January 25, 2022 but, with a pediatric extension, is now set to expire on July 25, 2022.

144. The '106 patent specification says that "the present invention relates to therapeutic combinations of peroxisome proliferator-activated receptor (PPAR) activator(s) *and* sterol absorption inhibitor(s) for treating vascular conditions (including atherosclerosis)" (emphasis added).

145. But neither of the claims in the '106 patent refers to combination use. Both claim pharmaceutical compositions of ezetimibe that were earlier disclosed in the RE'721 patent.[41] Given this and other earlier disclosures, the '106 patent is, and clearly was at the time of its issuance, invalid as obvious and/or for obviousness-type double patenting.

146. By this time, Merck/Schering had listed in the Orange Book the RE'721 azetidinone patent, the '966 combination-with-statins patent, and the '106 sterol non-absorption patent. The '365 process patent was not listed in the Orange Book, likely because process patents – unlike product or method of use patents – are not eligible for listing.

G. 2006: Glenmark files the first ANDA for generic Zetia.

147. On October 25, 2006, generic drug manufacturer Glenmark filed ANDA 78-560,

[41] The compound represented in Formula II of claims 1 and 2 of the '106 patent is ezetimibe. The table in claims 1 and 2 describing the composition lists lactose monohydrate (a sugar); microcrystalline cellulose (a starch); povidone (a disintegrant); crosscarmellose sodium (a dissolving agent); sodium lauryl sulfate (a foaming agent); and magnesium stearate (a release agent). All are conventional excipients and additives. The RE'721 specification explicitly refers to compositions made using conventional excipients and additives and conventional techniques, including "non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, anti-oxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers and the like."

seeking FDA approval to market an AB-rated generic version of Zetia.[42]

148. Merck's new chemical entity exclusivity expired on October 25, 2007, one year from the date Glenmark filed. Glenmark could not come to market until after that exclusivity expired.

149. Glenmark's ANDA included a paragraph IV certification to all of the patents then listed in the Orange Book: the RE'721 azetidinone patent, the '966 combination-with-statins patent, and the '106 sterol non-absorption patent.[43]

H. 2007-2008: Merck sues first-filer Glenmark; Glenmark counterclaims.

1. Early 2007: Merck sues Glenmark for infringing the RE'721 patent (only).

150. On or about February 9, 2007, Glenmark notified Merck of its ANDA filing and provided a detailed account of why the patents were invalid, unenforceable, and not infringed by Glenmark's ANDA product ("Glenmark's paragraph IV letter").

151. On March 22, 2007, Merck[44] sued Glenmark in the District of New Jersey. Merck alleged that Glenmark's ANDA infringed the RE'721 patent (only).

152. Merck did not sue Glenmark, in this suit or any other, for infringing the two other Orange Book listed patents, the '966 or the '106 patents. Merck apparently did not believe that it could realistically expect to win a lawsuit asserting that Glenmark's generic ezetimibe product would infringe the '966 combination-with-statins azetidinone patent or the '106 sterol non-

[42] October 25, 2006 was the first day allowed by law and regulation for would-be generic makers of Zetia to file an ANDA for that product; that date was one year before expiration of the five-year NCE exclusivity.

[43] Because the '365 process patent was not listed in the Orange Book, Glenmark did not need to certify to it in its ANDA.

[44] In this litigation, plaintiffs Schering Corporation and MSP Singapore Company LLC referred to themselves collectively as "Schering." We refer to them here as "Merck" instead.

absorption patent because those patents were inapplicable, invalid, or not infringed. Glenmark's product did not include a statin. And the unasserted '106 patent was, and is, invalid as obvious (as described above).

153. Under the Hatch-Waxman Act, Merck's filing of the RE'721 lawsuit – irrespective of its prospects of success – triggered a 30-month stay, running from the date Glenmark notified Merck of its paragraph IV letter. This stay prevented the FDA from granting final approval of Glenmark's ANDA until the earlier of (i) the expiration of the thirty-month stay, or (ii) entry of a final judgment that the RE'721 patent was invalid, unenforceable, and/or not infringed.[45]

154. Glenmark represented in a pleading early on that "[t]he amount at issue in this case is at least $1 billion, representing the anticipated sales by Glenmark of its generic product (and the corresponding loss of sales by [Merck])."

2. Spring 2007: Glenmark counterclaims, alleging the RE'721 patent is invalid and unenforceable.

155. On May 23, 2007, Glenmark answered, listed its affirmative defenses, and counterclaimed.[46] Glenmark sought a declaratory judgment that the RE'721 patent was invalid and/or unenforceable. Glenmark asserted that the RE'721 patent was invalid for double patenting, anticipation, obviousness, a lack of enablement, and inventorship issues. Glenmark also asserted that the RE'721 patent was unenforceable due to inequitable conduct and that

[45] Thirty months from the date Glenmark sent its paragraph IV certification is August 9, 2009. At one point during the litigation, Merck asserted that the 30-month stay expired on October 25, 2010. We allege here that generics would have entered as early as December 6, 2011, so the day on which the stay expired – under either interpretation – is before alleged generic entry and therefore irrelevant to the direct purchaser plaintiffs' claims.

[46] Glenmark filed a corrected answer on June 7, 2007. On March 10, 2008, Glenmark filed a first amended answer and counterclaim.

Merck was estopped or precluded from asserting infringement by reasons of actions taken and statements made to the PTO during prosecution of the application(s) that led to the RE'721 patent.[47] Glenmark refined these arguments as the litigation progressed.

156. *Invalid for inherent anticipation.* Glenmark argued that at least two compounds claimed in the RE'721 patent are inherent metabolites of a hypercholesterolemic compound (SCH48461) disclosed in an earlier Schering patent application. Merck had disclosed two compounds claimed in the RE'721 patent in an earlier patent application: International Application No. PCT/US92/05972, filed on July 21, 1992 and published on February 4, 1993 as WO 93/02048 (the "PCT'048 publication").[48] Upon ingestion, at least one of these earlier disclosed compounds, SCH48461 (disclosed as Example 9), is metabolized to form two hydroxyl-substituted compounds that are both claimed in the RE'721 patent. These metabolites inherently anticipate the claims of the RE'721 patent.

157. Under the doctrine of inherent anticipation, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference."[49]

158. Merck and Schering were well aware of the doctrine of inherent anticipation. That doctrine featured prominently in a case Schering brought against Geneva Pharmaceuticals for

[47] In Glenmark's first amended answer and counterclaim, filed on March 10, 2008, it added a claim asserting that the 497-day patent term extension Merck received for the RE'721 patent was invalid.

[48] The named co-inventors of PCT'048 are Duane A. Burnett, John W. Clader, Tiruvettipuram K. Thiruvengadem, Chou-Hong Tann, and Junning Lee. Burnett and Clader are named as co-inventors of the '721 patent. The publication date of the PCT'048 predates all applications to which the RE'721 claims priority.

[49] *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citing *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)), *reh'g denied*, 348 F.3d 992 (2003).

allegedly infringing a patent for the prescription drug Claritin. There, on August 8, 2002, the district court concluded that "the natural, inevitable production of metabolic DCL upon human ingestion of loratadine, although not fully appreciated by persons of ordinary skill in that field until more recently . . . , demonstrates that this process is an inherent characteristic or functioning of the use of loratadine, the subject of the '233 patent. Therefore, that patent inherently anticipates Claims 1 and 3 of the '716 patent, rendering them invalid." The district court observed that "this is not a new doctrine," and cited cases from the 1980s and 90s. The district court also noted that Schering's policy arguments to the contrary were "not persuasive" and that the Patent and Trademark Appeals Board's opinions Schering cited in support of its arguments that inherency by anticipation did not apply were "not consistent with the Federal Circuit law." The Federal Circuit later affirmed.

159. *Inequitable conduct for failure to disclose inherency.* Glenmark argued that Merck committed inequitable conduct during prosecution of the RE'721 patent by not disclosing the inherency of these metabolites to the PTO. Merck did not do so before the RE'721 patent issued, nor did it do so in any post-issuance communications with the PTO about the RE'721 patent.[50] Inequitable conduct is the atomic bomb of patent law; when found, the entire patent becomes invalid and/or unenforceable.

[50] The RE'721 patent issued on May 28, 2002. The district court *Schering v. Geneva* opinion issued on August 2, 2002. On August 14, 2002, Schering filed a Request for Certificate of Correction for the RE'721 patent with the PTO, seeking to correct the priority information recited in the RE'721 patent (likely to ensure that it was treated as an application filed under 35 U.S.C. § 371 and therefore had a later expiration date than the '365 and '966 patents). On December 12, 2002, Schering filed a Request for Patent Term Extension with the PTO. On August 1, 2003, the Federal Circuit affirmed the district court's inherency decision. Schering's request for patent term extension was not resolved until August 29, 2006. Between May 28, 2002 and the conclusion of the patent term extension in 2006, Schering never mentioned inherency or either *Schering v. Geneva* decision in any of its communications with the PTO about the RE'721 patent.

160. Glenmark identified several publications describing the work that the Merck scientists did to investigate compound SCH48461, its metabolites and metabolite-like analogues, that supported its inherency argument – many authored or reviewed by Merck scientists who were also inventors of the RE'721. Merck never disclosed these publications to the PTO during prosecution of the RE'721 patent. Glenmark argued that these publications would have been material to the PTO when examining the RE'721 patent. That Merck withheld them, and key information they contained, reflects deceptive intent.[51] These publications included:

- Margaret Van Heek et al., Abstract, *Isolation and Identification of the Active Metabolite(s) of SCH48461 and Possible* in Vivo *Mechanism of Action for their Inhibition of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Van Heek 1995 abstract");

- Harry R. Davis, Jr. et al., Abstract, *The Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor SCH 58235 Alone and in Combination with HMG CoA Reductase Inhibitors*," Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Davis 1995 abstract");

- Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Rosenblum 1995 abstract");

- John W. Clader et al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996) (the "Clader 1996 publication");[52]

- Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271

[51] Rather than repeat the details of Glenmark's discussion of these publications here, FWK incorporates by reference ¶¶ 30-171 of Glenmark's First Amended Answer and Counterclaims (*Schering Corp. v. Glenmark Pharm., Inc., USA*, No. 07-cv-01334 (D.N.J. Mar. 10, 2008), ECF No. 54), attached as Exhibit A.

[52] Received June 7, 1996. Abstract published in *Advance ACS Abstracts* on August 1, 1996.

(1996) (the "Dugar 1996 publication");

- Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997) (the "Van Heek 1997 publication");[53]

- Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998) (the "Rosenblum 1998 publication").[54]

161. *Inequitable conduct re patent term extension.* Glenmark argued that Merck further committed inequitable conduct when seeking the RE'721 patent term extension, by not disclosing that at least some claims were invalid due to inherent anticipation. Merck sought to extend the term of the RE'721 patent claims after *Schering v. Geneva* was decided, knowing that claims it sought to extend were invalid under the doctrine of inherent anticipation.

162. *Invalidity for lack of enablement.* Glenmark argued that the RE'721 patent does not teach one skilled in the art how to use ezetimibe to prevent atherosclerosis without further experimentation, which renders claims invalid for lack of enablement.

163. To be enabled, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Articles published after a patent application's filing date *can* establish a lack of enablement.

164. *Failure to name inventors.* Glenmark argued that Merck may have failed to name all inventors, and took discovery on the issue. On May 10, 2006, the industry group Pharmaceutical Research and Manufacturers of America ("PhRMA") presented the Discoverers

[53] Received for publication on February 13, 1997. Accepted for publication on June 30, 1997. Included in the October 1997 issue.

[54] Submitted October 16, 1997.

Award for contributions to the discovery of ezetimibe to three individuals: Harry R. Davis, Jr., Dr. Margaret Van Heek, and Kevin B. Alton. Merck had nominated all. None were listed as inventors on the RE'721 patent.

165. *Lack of proper reissue.* Glenmark argued that reissue was improper, and thus the reissued claims were invalid, for failure to identify an error in the '115 patent of the type that may be properly corrected through reissue.

166. *Invalidity for obviousness-type double patenting.* Glenmark argued that the subject matter claimed in the RE'721 patent was not patentably distinct from matter claimed in Merck's earlier issued (and earlier expiring) '365 patent. As a result, at least some claims of the RE'721 patent were alleged to be invalid for obviousness-type double patenting.

I. Spring 2009: Glenmark receives tentative approval, and Merck receives new regulatory exclusivities.

167. On April 24, 2009, the FDA gave tentative approval to Glenmark's Zetia ANDA. It did so within the 30-months allotted by statute, and so secured Glenmark's first-filer 180-day exclusivity.

168. At the time Glenmark received tentative approval, the 30-month stay prevented Glenmark from launching.

169. In 2009, the FDA listed a new exclusivity in the Orange Book – for adding pediatric information to the label – which expired on June 5, 2011. The FDA also added pediatric exclusivities to all listed patents and exclusivities, which expired on December 6, 2011.

J. Summer 2009: Glenmark seeks partial summary judgment on two discrete legal issues.

170. In separate motions for partial summary judgment in July of 2009, Glenmark raised two discrete legal issues as to which it did not believe there to be any disputed issues of facts. At that time, trial was scheduled for May of 2010.

171. *Motion re Reissue Error*. Glenmark argued that the RE'721 patent was invalid for Merck's failure to identify an error of the type that may be properly corrected in reissue. Glenmark argued that the '115 patent was not, as issued, wholly or partly invalid, and that therefore it could not be properly reissued under 35 U.S.C. § 251.

172. *Motion re Double-Patenting.* Glenmark argued that 12 of the 13 claims in the RE'721 patent were invalid by reason of obviousness-type double patenting, in light of Merck's earlier issued '365 patent.

173. Neither Glenmark nor Merck moved for summary judgment on any of the other issues or arguments listed above (e.g., inherent anticipation, inequitable conduct, lack of enablement, or failure to name inventors). From the fact that Glenmark did not move for summary judgment on other grounds one can only infer that Glenmark (1) preferred to present its other arguments to the finder of fact at trial or (2) believed there to be disputed issues of fact between the parties that would prevent its arguments from being conclusively resolved at the summary judgment phase.

K. Fall 2009: Merck obtains the second sterol absorption patent (the '058 patent).

174. On November 3, 2009, while the Glenmark summary judgment motions were pending, Merck's Application No. 10/998,400[55] issued as U.S. Patent No. 7,612,058, Merck's second sterol non-absorption patent.

175. The '058 patent is subject to a terminal disclaimer. According to Merck, it originally was set to expire on January 25, 2022, and with a pediatric extension is set to expire on July 25, 2022.

[55] On November 29, 2004, Schering filed Application No. 10/998,400 as a divisional of the '968 application, seeking another inhibition of sterol absorption patent. The primary examiner was again San-Ming Hui.

176. The ’058 patent includes 10 claims. All cover methods of treating conditions associated with high cholesterol (e.g., atherosclerosis, diabetes, obesity) comprising administering a pharmaceutical composition consisting of the same compound and routine pharmaceutical additives described in the ’106 patent (Formula II, ezetimibe). The ’058 patent was at the time it was issued, and at all times thereafter, invalid for the same reasons as the ’106 sterol non-absorption patent. Like the ’106 patent, the named inventor is Philip Wing-Kee Cho.

L. Spring 2010: Par partners with Glenmark regarding generic Zetia.

177. On April 30, 2010, Glenmark and Par entered into a Marketing and Distribution Agreement (the “Glenmark/Par Distribution Agreement”) “appoint[ing]” Par to the “exclusive distributor to market, distribute and sell” Glenmark’s generic Zetia in the United States. In exchange for, among other things, a [redacted] up front payment to Glenmark and Par’s promise to pay Glenmark [redacted] of its net profit on all of its subsequent sales of Glenmark’s generic Zetia in the United States, Par knowingly and voluntarily entered into [redacted] with Glenmark.

178. The Glenmark/Par Distribution Agreement confirms that Glenmark provided Par “all documents or materials in its possession or control”[56] relating to the “ANDA Litigation,” defined as the “patent infringement suit with Schering-Plough (now Merck), U.S., Civil Action No. 2:07-cv-01334 in the United States District Court for the District of New Jersey, involving U.S. Patent No. RE37,721” (i.e., the Merck-Glenmark patent infringement litigation).[57] The Glenmark/Par Distribution Agreement required Par and Glenmark to “jointly” make “all material decisions” in the Merck-Glenmark patent infringement litigation or any other litigation involving

[56] GLENMARK-ZETIA-00056715, §7.2.3.

[57] *Id*. at Preliminary Statements, ¶ B.

generic Zetia. Specifically, Section 9.2.2 of the Glenmark/Par Distribution Agreement, entitled "Decisions" provided:

> 9.2.2 Decisions. Glenmark shall keep Par reasonably informed regarding material developments with respect to any Litigation. Glenmark shall continue to control the defense of the Litigation, *except that all material decisions with respect to the Litigation shall be made jointly by Glenmark and Par*; provided, however, that if the Parties fail to promptly agree upon a course of action, Glenmark's decision shall control any Litigation as well as any settlements thereof Glenmark and Par, to the extent necessary to protect and preserve the attorney-client privilege between Glenmark and its counsel, shall enter into a common interest and/or joint defense agreement.[58]

179. Under the terms of the Glenmark/Par Distribution Agreement, Glenmark could not settle its lawsuit with Merck without Par's "written consent." And if any such settlement were to occur, Glenmark was required to share any proceeds [redacted]

> 9.23 Settlement Proceeds. Neither Party shall enter into a settlement with a third party related to the marketing or Launch of the Product without the prior written consent of the other Party. In the event that the Parties enter into a compromise, settlement or other resolution of any Litigation or threatened litigation, Glenmark shall pay Par [redacted] of any amount received by Glenmark pursuant to such compromise, settlement or resolution.[59]

180. The Glenmark/Par Distribution Agreement also required Par to consult with Glenmark regarding marketing, pricing, and distribution decisions, and explicitly established a Steering Committee comprised of "an equal number of duly qualified representatives of Par and

[58] *Id.* at §9.2.2 (emphasis added). The Glenmark/Par Distribution Agreement also required Par and Glenmark to share "equally" in all going forward litigation costs, expenses, and attorney fees associated with the Merck-Glenmark patent infringement litigation or any other litigation involving generic Zetia. *Id*. at §9.2.1.

[59] *Id.* at §9.2.3.

Glenmark . . . with the necessary authority to deal with and make decisions concerning the matters within the Steering Committee's authority," including but not limited to:

a. "overall strategy for the marketing of the Product [generic Zetia]";

b. "review and advise on the marketing plan";

c. "monitor the activities and performance of Par related to the marketing Plan";

d. "review and advise on decisions in connection with the marketing plan"

e. "review and advice on major amendments to the marketing plans, including without limitation, with respect to timelines and budgets";

f. "discuss pre-Launch marketing plans and strategies (including the estimated Launch Date)"; and

g. "review and advise on life cycle management plans for the Product [generic Zetia] after the Product has been Launched or has been actively planned for Launch".[60]

181. The Glenmark/Par Distribution Agreement required Glenmark and Par to establish the Steering Committee within 30 days of the agreement's execution, and to "meet a minimum of twice a year on an approximately semi-annual basis" and would be chaired by a Glenmark representative for the entire period "[p]rior to the pre-Launch commercialization planning" but thereafter by a Par representative.[61]Execution of the Glenmark/Par Distribution Agreement made Par a [redacted] with Glenmark concerning the Merck-Glenmark litigation,

[60] *Id.* at §3.2.

[61] *Id.* at §3.5.

its maintenance and settlement, and any settlement proceeds and/or benefits, including on sales of Glenmark's generic Zetia in the United States.

182. Par performed under the Glenmark/Par Distribution Agreement by, in part, not taking any action that could undermine the conspiracy's ultimate aims, by distributing generic Zetia in the United States starting in December 2016 as contemplated by defendants' unlawful reverse payment agreement.

183. Likewise, Glenmark (which retained all rights and ownership of its Zetia ANDA),[62] performed under the Glenmark/Par Distribution Agreement by refraining from any generic Zetia manufacture, sale, or distribution inconsistent with the conspiracy's agreements, including the December 12, 2016 launch date for generic Zetia, and Par's distribution of generic Zetia in the United States as contemplated by the unlawful distribution and reverse payment agreements.

M. Summer 2010: Merck and Glenmark/ Par settle with a reverse payment.

1. The Court sends Glenmark's double-patenting argument to trial.

184. On April 19, 2010, the Honorable Jose L. Linares of the U.S. District Court for the District of New Jersey issued opinions addressing each of Glenmark's motions for partial summary judgment. First, the court granted Glenmark's motion on invalidity, agreeing with Glenmark that reissuance of the '115 patent had been improper because Merck had failed to identify the kind of purported error that can be corrected in reissue. This functionally threw out claims 10-13, which claimed ezetimibe expressly and had been added in reissue. Merck moved for reconsideration of this order on April 30, 2010.

185. On the same day, the court denied Glenmark's second motion for partial summary

[62] *Id.* at §6.1.1.

judgment (obviousness double patenting), concluding that disputed issues of fact as to whether, at the time of the '365 patent, alternative processes for making the claimed azetidinone compounds existed. The court did not hold that there was no double patenting. Rather, the court simply concluded that the issue of double patenting should be resolved by the finder-of-fact at trial, based on a full evidentiary record.

2. Two days before trial, Merck and Glenmark/Par agreed to settle by providing a reverse payment to Glenmark/ Par.

186. Trial was scheduled to begin on May 12, 2010. At issue were Glenmark's affirmative defenses and counterclaims, including its assertion that claims 1 through 9 were unenforceable because of Merck's intentional failure to disclose to the PTO either (1) compounds claimed in the RE'721 were naturally occurring metabolites of SCH46481 (and therefore inherently anticipated by earlier disclosures) or (2) the disqualifying prior art publications by Merck's own scientists that had been hidden from the PTO.

187. On May 10, 2010, two days before the scheduled start of trial, Merck and Glenmark entered into an agreement that settled the patent infringement lawsuit (the "Merck-Glenmark/Par Settlement Agreement") but, as later events would show, also unlawfully allocated the market for ezetimibe.

188. Merck and Glenmark agreed to entry of a consent judgment. In order to ensure there were no adverse rulings concerning the RE'721 patent as a result of the litigation, a condition of the settlement included that the parties seek to have the court vacate its partial summary judgment invalidating claims 10-13 for improper reissue. The parties gave the court a proposed order, along with the consent judgment vacating the partial summary judgment order on claims 10-13. That proposed order makes reference to the fact that the ruling of the Board of Patent Appeals and Interferences in *Ex parte Tanaka*, on which the Court based its ruling

invalidating claims 10-13, had been docketed for appeal.

189. The proceedings on entry of the consent judgment revealed that the parties had agreed that, subject to certain unrevealed caveats, Glenmark/Par would not enter the market with its generic Zetia product until December 12, 2016.

190. Including as expressed by the terms of the Glenmark/Par Distribution Agreement, Par knowingly agreed to the Merck-Glenmark/Par Settlement Agreement. The Glenmark/Par Distribution Agreement expressly prohibited Glenmark settling with Merck absent Par's express written consent. The Merck-Glenmark/Par Settlement agreement also expressly acknowledges some aspects of Par's role and participation in the conspiracy as, at minimum, the distributor of "Glenmark Product [generic Zetia] in the United States on or after the [unlawfully agreed-to] Entry Date."[63]

191. Par knowingly and voluntarily agreed to the terms of the Merck-Glenmark/Par Settlement Agreement and authorized its execution by Glenmark. By operation of the Glenmark/Par Distribution Agreement, Par and Glenmark were equal partners with Merck in the unlawful reverse payment agreement reflected in the Merck-Glenmark/Par Settlement Agreement.

192. Although the consent judgment referenced the settlement agreement, it was not docketed in the court record. The parties did not publicly reveal any of the remaining terms of that agreement at the time of the settlement. Nor have the other terms of that agreement ever been made public.

193. Certain terms of the Merck-Glenmark/Par Settlement Agreement were revealed only by later events. As a quid pro quo for Glenmark/Par's agreement to drop the patent

[63] MRKZETIA000000005, §1.19.

challenge and delay market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark/Par's eventual 180-day exclusivity period (the "no-AG agreement"). Par agreed, just as Glenmark agreed, to delay launching generic ezetimibe in consideration for Merck's promise not to launch an AG (and [redacted] of the ill-gotten gains). The existence of a no-AG agreement is inferred from the following facts:

194. First, Merck previously admitted that marketing an authorized generic is often in its economic interest. For example, speaking about another blockbuster drug, Fosamax, a Merck executive acknowledged that Merck's "authorized generic strategy" will "maximize the value of the franchise" after entry by generic competitors.

195. Second, Merck had a well-established history of launching authorized generics in the face of generic competition. Other branded drugs for which Merck or Schering has launched authorized generic versions include Blocadren, Clinoril, Cozaar, Diprolene, Lotrisone, Nasonex, Singulair (Oral Granules), Temodar, Blocadren, K-Dur 10, K-Dur 20, and Lotrimin AF.

196. Third, Zetia was a blockbuster drug, with sales in the billions at the time that a generic eventually launched in 2016. Absent Glenmark and Par's reciprocal agreement to delay entering the market, launching an authorized generic would have been in Merck's financial interest.

197. Fourth, when Glenmark/Par launched the Glenmark generic on December 12, 2016, Glenmark issued a press release describing its generic Zetia as "the first and only generic version" of Zetia in the United States.

198. Fifth, when Glenmark/Par eventually did launch generic Zetia in late 2016, Merck did not launch an authorized generic during Glenmark/Par's 180-day ANDA-exclusivity period. The absence of an authorized generic on the market by Merck in late 2016 and the first half of

2017 is strong evidence that Merck had made a contractual agreement with Glenmark not to launch such a product. During this time period – the first six months of generic launch – Merck stood to earn hundreds of millions of dollars from an AG launch.

199. Sixth, Glenmark reported to its shareholders in May 2017 that it had expected before launching the product that it would take well more than 58% of the combined brand and generic Zetia sales that it had in fact achieved by then. As noted in detail above, in the absence of a no-AG pact, a reasonable pharmaceutical company would realistically expect to take only about a 40% market share during that time period (one half of the standard 80% erosion rate).

200. Given Merck, Glenmark's, and Par's choice to conceal the terms of their unlawful agreement, the absence of an AG launch for generic Zetia could be publicly learned only at the time that Merck failed to undertake such a launch – late December 2016 and the first six months of 2017. Short of some disclosure of the confidential settlement agreement, existence of the no-AG agreement could not have been known until Glenmark launched its generic in 2016 and Merck failed to launch an AG product.

201. The no-AG agreement was a payment to Glenmark and Par from Merck worth substantially more than Glenmark and Par could have earned if they had come to market with generic Zetia in 2011. Glenmark/Par could not have obtained a no-AG agreement even had Glenmark won the patent infringement litigation. By delaying generic entry for more than five years, and thereby obtaining the no-AG agreement from Merck, Glenmark, and Par was ensured six months of exclusive generic sales, free from competition from Merck's authorized generic or any other generic competitors. Par, Glenmark's [redacted], retained [redacted] of the unlawful gains on Glenmark generic Zetia sales that resulted from Merck's no-AG promise. The other [redacted] of those unlawful gains went to Glenmark.

202. For Merck, the benefits of the no-AG agreement were enormous. While it would forgo six months of profits on an authorized generic, in turn it would enjoy more than five years of monopoly profits selling much more expensive and profitable branded Zetia.

203. At this pre-discovery stage, the value of the reverse payment agreement to Merck and Glenmark/Par can be calculated using the known economics of the pharmaceutical industry.

204. The reverse payment agreement was entered into in May 2010. That agreement delayed Glenmark/Par's generic entry until December 2016. Absent the reverse payment, generic entry would have occurred much sooner than it did, and as early as December 6, 2011.

205. By that time, other than the RE'721 (addressed momentarily), no other impediments existed to the prompt approval and launch of generic Zetia.

206. First, Glenmark's ANDA had already received FDA tentative approval. In effect, Glenmark had met all preconditions for final FDA approval other than the 30-month stay that Merck's enforcement of the RE'721 posed against Glenmark.

207. Second, no other patents held by Merck would forestall generic entry. The '966 patent had claims only to combination products, but generic Zetia is not a combination product, and Merck never enforced the '966 patent against Glenmark. The '106 and '058 sterol non-absorption patents were obvious in light of the RE'721 disclosures, and Merck never enforced those patents against Glenmark. The '365 patent was limited to the narrow processes set out in that patent, and Merck never enforced the '365 patent against Glenmark.

208. Third, no other exclusivity existed after December 5, 2011. The NCE exclusivity expired in 2007. Two other exclusivities – an indication exclusivity I-493 and a pediatric exclusivity M-54 – were likely capable of being carved out of any generic label, and in any event had expired by December 5, 2011.

209. As to the RE'721 patent, in the absence of the reverse payment and with Merck and Glenmark/Par acting as reasonable, economically rational companies, generic entry would have occurred much sooner than it did – as early as December 6, 2011 – on a date to be determined by the jury at trial.

210. First, absent the reverse payment, reasonable, economically rational companies in the position of Glenmark/Par and Merck may still have settled the litigation, but without a reverse payment, and with an earlier agreed entry date. That agreed entry date would have been based on the merits (but really the lack thereof) of Merck's RE'721 infringement claims – claims that had no merit. As a result, an arms' length settlement between economically rational, law-abiding companies would have led to an agreed entry date occurring much sooner than it did, and as early as the expiration of any lawful exclusivity, i.e., December 6, 2011.

211. Second, and alternatively, absent the reverse payment Glenmark would have won the trial scheduled to start in May 2010. A finder of fact would have concluded that (for the reasons described above) Merck failed to prove that Glenmark infringed a valid patent for one or more of the following reasons:

- Merck (through the inventors, agents, and others with a Rule 56 duty) committed inequitable conduct by intentionally and deceptively hiding the fact that the RE'721 claimed compounds that were naturally occurring metabolites of SCH 48461 (and therefore inherently anticipated by its earlier disclosure in PCT'048), which would render the entire RE'721 patent invalid or unenforceable);
- Regardless of whether Merck committed inequitable conduct, the claims of the RE'721 patent were invalid for inherent anticipation; and
- The RE'721 patent was invalid for obviousness-type double patenting over the '365 patent.

212. A reasonable, economically rational company in the position of Glenmark/Par would have launched generic Zetia soon after a district court ruling in its favor and the expiration

of any other, lawful exclusivity.

213. Without the large and unjustified payment, several additional generics would have come to market after Glenmark/Par's 180-day exclusivity ended – as early as June 6, 2012, and in any event much earlier than June 12, 2017. Merck's last regulatory exclusivity ran on December 6, 2011. By then, Glenmark/Par would have resolved the RE'721 infringement claims by either winning at trial, or settling on competitive terms (without a payment), or launching at risk. And Merck had not accused Glenmark of infringing any other Orange Book listed patents for Zetia.

214. In the absence of the large and unjustified payment, Merck would have launched its authorized generic version of Zetia at or around the same time that Glenmark/Par launched its generic – as early as December 6, 2011 – on a date to be determined by the jury.

3. The value of the no-AG agreement to Merck.

215. With generic entry in December 2011, Merck would have lost about 80% of its branded sales. But without generic entry, it kept all those sales – and continued to enjoy those branded sales until the end of 2016.

216. Because Glenmark was the first ANDA filer, its agreement not to launch generic Zetia until December 2016 created a competition bottleneck wherein no other generic company could market a generic Zetia product until 180 days after Glenmark/Par launched its generic product. In establishing a bottleneck using Glenmark/Par, Merck maximized the potential for it to maintain its monopoly on Zetia for about five years longer than it otherwise would have.

217. Determining the value to Merck of the no-AG promise is a matter of estimating the additional branded sales it enjoyed during that five-year delay compared to the sales it would have made (a) from the reduced sales of branded Zetia, plus (b) the sales of its authorized generic during the first six months of generic competition starting in December 2011.

218. Sales of branded Zetia in 2011 totaled $1.298 billion. Based on well documented patterns of sales and pricing related to generic entry, Merck's authorized generic and Glenmark/Par's generic, combined, would have captured about 80% of the amount of branded sales in the first six months, with each of those companies splitting the generic sales 50/50 (therefore, 40% each of the brand share). Those generics would have sold at about 50% of the price of the brand. Using these assumptions, the value of the authorized generic sales by Merck in the first six months following generic entry in December 2011 would have been about $129.8 million ($1.298 billion times 0.5 [for the first six months] times 0.4 [share of the generic sales] times 0.5 [generic price].[64]

219. Even with generic entry, Merck could still expect to sell some branded product -- about 10% (or less) of its previous volume per year. So the revenues to Merck in the event of timely generic entry in, say, late December 2011, over the five-year time period reasonably would have been expected to be about $778.8 million ($1.298 billion baseline times 0.1 [for annual branded sales] times 5 [for five years] plus $129.8 [for AG sales in the first six months]).

220. As a result of the no-AG agreement, however, Merck enjoyed full branded sales from December 2011 through December 2016 without competition from Glenmark's generic (or any other generic manufacturer). If one expected no growth in sales, then Merck would have about $6.490 billion in gross sales for Zetia over that five-year period (or about $5.7 billion more than it would receive under competitive conditions). Publicly available information indicates that total sales for branded Zetia during this entire time period actually amounted to more than $9.1 billion (or about $8.3 billion more than it would receive under competitive conditions).

[64] $1,298,000,000 × 0.50 (1/2 year) × 0.80 (generic penetration) × 0.50 (generic price) × 0.50 (split sales volume with Glenmark) = $129,891,200.

221. As a result of the no-AG agreement therefore, Merck enjoyed between about $5.7 billion to about $8.3 billion in additional sales of branded Zetia, all at a cost of about $129.8 million in lost authorized generic sales during the first six months of generic entry.

4. The value of the no-AG promise to Glenmark and Par.

222. The value of the no-AG agreement from Glenmark and Par's perspective is a matter of estimating the additional sales they made during the six month generic exclusivity period in 2016 compared to the sales they would have made in the first six months of generic competition starting in December 2011 when, without the benefit of the no-AG agreement, they would have faced competition from Merck's authorized generic.

223. Under competitive conditions, the calculation of Glenmark/Par's sales during the first six months of generic competition starting in December 2011 is identical to the calculation for Merck's authorized generic during this period, because the same assumptions apply to Glenmark/Par's generic as to Merck's. Thus the value of generic sales by Glenmark/Par in 2011, facing competition from Merck's authorized generic, would have been approximately $129.8 million.

224. Under the anticompetitive conditions of the no-AG promise, however, Glenmark and Par stood in a far better position financially. Glenmark and Par would now collectively (a) get 100% (not 50%) of the generic sales in the first six months of generic launch (because there was no authorized generic taking market share); (b) be able to sell that generic during those months for about 90% (not 50%) of the branded price (because there was no authorized generic driving down price); and (c) be able to have its generic product enter a market that had grown in size over the five-year delay period. Indeed, by 2016 annual sales of branded Zetia had grown to $2.6 billion.

225. Without competition from Merck's authorized generic, Glenmark and Par could

expect to capture 80% of the sales of the branded product in 2016, and likely would have priced its generic product at about 90% of the brand's price. As a result, during its six-month exclusivity period in 2016, without competition from Merck's authorized generic, Glenmark and Par collectively realized about $936 million in generic sales ($2.6 billion times 0.5 [1/2 year] times 0.8 [generic penetration] times 0.9 [generic price]). Par's share of those unlawful gains would have amounted to [redacted]

226. Thus, the agreement with Merck to delay Glenmark/Par's launch of generic Zetia until December 2016 was worth approximately $806 million in *additional* sales to Glenmark and Par [redacted], compared to sales they would have made beginning in December 2011 without the benefit of the no-AG agreement ($936 million less $129.8 million). The no-AG payment from Merck made delayed generic entry quite lucrative for Glenmark and Par.

227. Even if the parties did not foresee the meteoric rise in the sales of the branded product between 2011 and 2016, the no-AG promise was still a lucrative one for Glenmark/Par from that pessimistic perspective in 2011. If one assumes that the sales of branded Zetia remained flat at 2010 levels (when the parties entered into their reverse payment agreement) until Glenmark entered with its generic in 2016, the no-AG promise was still worth an additional $225 million to Glenmark and Par respectively [redacted] over what they would have made launching Glenmark's generic in December 2011.[65] Whether or not one assumes that the sales of branded Zetia would have remained flat at 2010 levels, the no-AG pact unlawfully delivered to both Glenmark and Par more than they could have obtained *even if Glenmark had won* the patent infringement litigation.

[65] $985,823,000 (2010 brand sales) × 0.5 (six months) × 0.8 (generic penetration) × 0.9 (generic price) = $354,896,280 – $129,891,200 = $225,005,080.

N. 2010-2013: Merck seeks another reissue and sues more generics.

1. Summer 2010: Merck admits invalidity and seeks reissue of the RE'721 patent.

228. On June 9, 2010, within a month after its settlement with Glenmark/Par, Merck applied to the PTO for reissuance of the RE'721 patent. Again, to obtain reissue, the applicant must identify an error and attest, under oath, that the original patent is wholly or partly inoperative or invalid. Merck and its agents admitted that the RE'721 patent was invalid, citing inherent anticipation as the reason (as Glenmark had argued).

229. In the required declaration accompanying its reissue application, Mark Russell, legal director of patents for Schering Corporation attested to an error, and conceded that Glenmark's inherent anticipation argument was correct:

- "I have reviewed and understand the content of the above identified specification, including the claims . . . ."
- "I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below . . . by reason of the patentee claiming more than he had the right to claim in the patent."
- "At least one error upon which reissue is based is described as follows: At least one claim of RE37,721 E is potentially inherently anticipated by International published patent application WO 93/02048, filed July 21, 1992 (PCT/US92/05972) and published February 4, 1993 ("the '048 PCT publication"). See also European patent application EP 0524595 A1. In infringement litigation involving RE37,721 E, defendants have alleged that the PCT'048 publication recites, in Example 9, a compound, that when administered to mammals, as also reported in the PCT'048 publication, metabolizes into one or more compounds that fall within the scope of at least claims 1 of RE37,721 E."
- "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed."

230. In Merck's preliminary remarks, attorneys Carl A. Morales and James F. Haley, Jr. of Ropes and Gray LLP, attorneys/agents for reissue applicants, made similar statements about inherent anticipation and invalidity being the basis for seeking reissue, and proposed amendments to the claims that ostensibly addressed these problems, namely cancelling claims 1-2 and 4-6 and amending claims 3 and 7-9.

2. Summer 2010: Merck sues Mylan and Teva for infringing the RE'721 patent; both counterclaim.

a. The *Mylan* litigation.

231. In or about April 2010, Mylan Pharmaceuticals, Inc. filed a paragraph IV ANDA for generic Zetia.

232. Mylan sent its paragraph IV notice for Zetia to Merck on May 25, 2010.

233. On June 16, 2010, a week after it filed its latest reissue application, Merck sued Mylan for infringement of the RE'721.[66]

234. Mylan counterclaimed, seeking declarations that both patents were invalid and unenforceable, also asserting claims for damages under the federal antitrust laws and state unjust enrichment laws. Mylan raised many of the arguments initially raised by Glenmark.

b. The *Teva* litigation.

235. On July 21, 2010, Teva Pharmaceuticals notified Merck that Teva had filed ANDA 78-724 for approval to make generic Zetia, including a paragraph IV certification that the

[66] Merck initially asserted that Mylan's Zetia product infringed the '966 patent, but withdrew that allegation part way through the litigation. Mylan had earlier filed an ANDA for Vytorin, a Merck product also marketed to combat high cholesterol that includes ezetimibe as one of two active ingredients. Merck's patent infringement suit against Mylan claiming infringement of the RE'721 and '966 patents by the Vytorin ANDA had been filed in December of 2009, and was pending before Judge Linares in the District of New Jersey at the time of the Merck-Glenmark/Par settlement. The Vytorin and Zetia cases against Mylan were consolidated for all purposes in September 2010.

listed patents were invalid and unenforceable.

236. On September 1, 2010, Merck filed suit against Teva for infringement of the '966 and RE'721 patents in the District of New Jersey. Later that month, Merck formally agreed not to assert the '106 and '058 patents against Teva.

3. Spring 2011: The Federal Circuit functionally overturns the *Glenmark* "error" summary judgment decision.

237. In April 2011, shortly before the '115 patent was reissued for a second time, the Court of Appeals for the Federal Circuit reversed the Board of Patent Appeals and Interferences' ruling in *Ex parte Tanaka*. In *Tanaka*, the Federal Circuit recognized "the narrow rule" permitting applicants to add "dependent claims as a hedge against possible invalidity," noting that this rule "has been embraced as a reasonable interpretation of the reissue statute by this court and its predecessor for nearly fifty years."[67]

238. While this decision effectively overturned the rationale behind the earlier *Glenmark* summary judgment about the technical requirements for invoking the reissue statute, it did not in any way undermine any of Glenmark's other arguments regarding invalidity or unenforceability of the RE'721.

4. Summer 2011: Merck obtains reissuance of RE'721 patent (RE'461).

239. On June 14, 2011, the RE'721 patent was reissued as U.S. Patent No. RE42,461.

240. The RE'461 patent as reissued (or as re-reissued in this case) included only claims 8 through 13, and parts of claims 3 and 7, of the RE'721 patent.

5. Summer 2011-2012: The Mylan and Teva litigations resolve.

a. 2011: Schering and Teva settle.

241. On July 7, 2011, before any substantive rulings in the case and while its parallel

[67] *In re Tanaka*, 640 F.3d 1246, 1251-52 (Fed. Cir. 2011).

case against Mylan was pending, Merck settled with Teva. Judge Linares entered a consent judgment that prohibited Teva from launching generic Zetia before April 25, 2017. No specific terms of the settlement were made public.

b. 2011: The Court denies Merck's motion for summary judgment of inequitable conduct.

242. On July 25, 2011, Merck filed an amended complaint against Mylan, substituting the newly reissued RE'461 patent for the RE'721 patent.

243. On August 19, 2011, Mylan filed an answer, affirmative defenses and counterclaims to Merck's amended complaint. In addition to invalidity based on inherent anticipation and unenforceability based on failure to disclose prior art, Mylan also alleged that the patents were unenforceable because of an intentional failure to disclose one of the inventors of ezetimibe.

244. On August 22, 2011, the court denied Merck's motion for judgment on Mylan's defense of inequitable conduct for failure to disclose prior art to the PTO, holding that "Mylan has put forth sufficient indirect and circumstantial evidence from which a reasonable fact finder could conclude that Schering had knowledge of the materiality of the withheld prior art," and that "a deliberate decision to withhold that information could . . . be reasonably inferred from the evidence already presented."[68]

245. On the same day, Judge Linares granted in part Merck's motion for summary judgment against Mylan, ruling that Mylan's ANDA did infringe claims 3, 10, 11, and 12.

246. On September 30, 2011, Merck indicated that it would no longer be asserting any claims of the '966 patent against Mylan.

[68] The court also noted that "Schering does not appear to dispute that it had knowledge of the metabolite information during prosecution."

247. On November 18, 2011, Mylan sent a letter to the Court confirming that it would be withdrawing a defense, namely its claim "based on the non-disclosure of information demonstrating a relationship between compounds claimed in predecessor patents and metabolites of a prior art compound." This withdrawal "thereby reduc[ed] the issues to be tried before the Court on December 5, 2011." Mylan explained that this was done "in the interest of further streamlining the issues remaining for trial" and "having considered the time allotted by the Court for presentation of issues by the parties." Mylan also specifically clarified that it had "not withdrawn its additional defenses based on inequitable conduct, including those related to improper inventorship."

248. Mylan's choice to pursue the inventorship issue rather than other arguments raised earlier in the litigation does not reflect the relative substantive merits of those argument/defenses, or Mylan's own evaluation of them. Instead, the choice simply reflected the untenable position in which Mylan found itself: Mylan had a limited amount of time to present its case, so Mylan picked a single, discrete issue to try.

249. Mylan knew when it was deciding on its litigation strategy in fall 2011 that even if it won the patent litigation it would enjoy no regulatory or even de facto exclusivity. It knew that Zetia was a blockbuster drug, and that many other generic manufacturers had filed or would ultimately file ANDAs seeking to market generic Zetia. Mylan further knew that both of the previously announced Glenmark/Par and Teva agreements may have included so-called "acceleration clauses" that would permit Glenmark/Par and Teva to enter the market as soon as any other generic manufacturer – such as Mylan – entered. And it knew that, in order to trigger Glenmark's 180-day exclusivity, it would have to prevail in the patent case all the way through the Federal Circuit. Thus, regardless of the time and resources that Mylan poured into trying to

win the patent litigation, the most it could hope to win would be (at best) a one-third or one-fourth share or (at worst) a one-seventh share of sales made at a price driven to down near marginal cost. Mylan's litigation strategy reflected the choice of not necessarily the best substantive defense, but the cheapest and fastest within the practical constraints.[69]

6. 2012: After a trial, the *Mylan* court found no inequitable conduct on inventorship (only).

250. Judge Linares held a bench trial in December 2011, solely on the issue of the claimed unenforceability of the RE'461 patent due to Merck's alleged inequitable conduct based on Merck's alleged misrepresentation of the inventorship of the RE'461 patent. The trial did not address any allegations that the RE'461 patent was invalid as obvious over prior art, or any allegations of inequitable conduct based on Merck's failure to disclose invalidating prior art.

251. On April 27, 2012, the court ruled that Mylan had failed to prove inequitable conduct on the inventorship issue and therefore that the RE'461 patent was not invalid or unenforceable on that basis.[70]

252. Later, on August 7, 2013, Mylan's ANDA for Zetia received tentative approval from the FDA. To date, Mylan has not launched a generic version of Zetia in the U.S.

7. 2012-2013: Schering sues Sandoz; Sandoz counterclaims; the parties settle.

253. In August 2012, Sandoz notified Merck that Sandoz had filed ANDA 203-931 for approval to market generic Zetia.

[69] Mylan was the first-filer with respect to another drug (Vytorin) involving the same patents at dispute in its Zetia litigation against Merck. But Mylan knew by Fall 2011 that: (1) it would not be entitled to 180-day exclusivity with respect to Vytorin because it would fail to get timely FDA tentative approval; and (2) other generic manufacturers would enter the market with generic Vytorin before or at the time that Mylan entered, even if it won the Vytorin patent case.

[70] Mylan appealed the verdict, but on February 7, 2013 the Federal Circuit Court of Appeals affirmed.

254. On September 27, 2012, Merck sued Sandoz for infringement of the RE'461 patent in the District of New Jersey. In its amended complaint filed May 29, 2013, Merck alleged that the purpose of Sandoz's ANDA submission was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's generic Zetia prior to the expiration of the RE'461, '966, '106, and '058 patents. In its answer to the amended complaint filed July 26, 2013, Sandoz admitted that it had sought approval to manufacture and sell generic Zetia prior to the expiration of those patents, and further admitted that Sandoz intended to manufacture and sell generic Zetia "immediately and imminently upon approval of ANDA No. 203931 in light of potential third party exclusivity rights." Sandoz pleaded affirmative defenses including the unenforceability and invalidity of the RE'461 patent.

255. Sandoz also counterclaimed for a declaratory judgment of the unenforceability of the RE'721 and RE'461 patents, the invalidity and Sandoz's non-infringement of one or more of the claims of those two patents as well as the '106 and '058 patents. Sandoz alleged, inter alia, that all the claims of the RE'721 and RE'461 patents were unenforceable due to inequitable conduct because Merck had "failed to disclose publications concerning metabolites of a prior art compound (compound SCH 48461)." Specifically, Sandoz alleged that the publications Merck withheld during prosecution of the RE'721 and RE'461 patents described "metabolic studies of SCH 48461 from which the examiner could determine the structure of metabolites of SCH 48461, and that relevant metabolites were inherently formed by the preparation and administration of SCH 48461, as disclosed in [the PCT'048] patent." Sandoz also alleged that the Van Heek 1997 article had claimed the discovery of ezetimibe in conjunction with Dr. Rosenblum in 1995, and described the "large chemical synthesis program [that] evolved to discover a more potent backup compound for SCH 48461," including the addition of "[a]

benzylic hydroxyl group … to SCH 53695 and several sites that were readily metabolized in SCH 48461 were blocked with fluorines resulting in [ezetimibe]." Sandoz additionally averred that the Dugar 1996 article, the Rosenblum I 1995 abstract, and the other prior art publications discussed above had specifically disclosed that two disclosed compounds, dubbed compound 57a and compound 58, were metabolites of SCH 48461 and thus inherently disclosed by the teachings of the prior art PCT'048 patent.

256. On September 3, 2013, the court ordered Sandoz to provide its ANDA to Merck by September 6, 2016 (ECF 46), and ordered Merck to file its response to Sandoz's counterclaims on or before September 17, 2013.

257. On September 5, 2013, before the pleadings in the case were closed, and before any further proceedings or any substantive rulings in the case, Merck and Sandoz settled all issues in the patent infringement litigation. Judge Linares entered a consent judgment prohibiting Sandoz from launching generic Zetia before April 25, 2017. No specific terms of the settlement were made public.

O. 2016: Glenmark and Par launch a generic form of Zetia; Merck does not.

258. Glenmark's ANDA 78-560 received final FDA approval on June 26, 2015. In its final approval letter, the FDA reconfirmed that Glenmark was entitled to 180-days of market exclusivity upon launch.

259. On December 12, 2016, Glenmark/Par launched its generic Zetia, which its press release of that date described as "the first and only generic version" of Zetia in the United States. Glenmark launched its generic product in partnership with Par (as planned).

260. From December 12, 2016, through June 12, 2017, Glenmark/Par's generic ezetimibe was the only generic version of Zetia sold in the U.S. market.

261. Merck refrained from launching an authorized generic version of Zetia during

Glenmark/Par's 180-day exclusivity period. It did so pursuant to the no-AG pact in the parties' unlawful agreement.[71]

P. 2017: 180 days later, five more generics launch.

262. On or about June 12, 2017 – the day Glenmark/Par's period of exclusivity expired – the FDA approved ANDAs for generic Zetia previously filed by seven competitor companies: Teva (ANDA 78-724), Sandoz (ANDA 203-931), Amneal (ANDA 208803), Apotex (ANDA 208332), Ohm Laboratories (ANDA 207311), Zydus (ANDA 204331), and Watson Laboratories (ANDA 200831).

263. Five of these manufacturers—Teva, Sandoz, Amneal, Apotex and Ohm Laboratories—launched a generic Zetia product in June 2017, shortly after receiving FDA approval. Zydus launched its generic Zetia product in August 2017. (Watson Laboratories had sold its generic drug business to Teva before June 2017 and so did not launch a generic Zetia product, but likely would have done so if the opportunity to launch occurred prior to Teva acquiring Watson's generic drug business.)

264. An eighth ANDA, filed by Aurobindo (ANDA 209838), was approved in August 2017 and launched the same month. An additional ANDA, filed by Alkem Laboratories (ANDA 209234), was approved in December 2017 and launched the same month.

265. Whereas only brand-name Zetia tablets were available to purchasers and

[71] Merck did not launch an authorized generic at the end of Glenmark/Par's 180-day exclusivity in June 2017. But the economics for Merck *after* Glenmark/Par's 180-day exclusivity were radically different than the economics for Merck would have been (absent the unlawful no-AG pact) *during* that exclusivity. After the exclusivity, Merck's authorized generic would have been one of at least seven generics on the market, competing for a margin driven down to near marginal cost. During Glenmark/Par's exclusivity, as noted in detail above, a Merck authorized generic would have been one of only two generics on the market, taking at least half the sales at margins that would have yielded more than a hundred million dollars in profits.

consumers before December 2016, and only brand-name Zetia and Glenmark/Par's generic tablets were available from December 2016 to June 2017, by July of 2017 there were six generics available to purchasers and consumers in addition to brand tablets, and by September of 2017 there were eight generics in addition to brand tablets.

266. The average retail price of ezetimibe tablets dropped from $10 per pill before Glenmark/Par's launch, to less than $1 per pill as of December 1, 2017, a 90% decrease.

267. Absent the no-AG promise, Merck would have launched an authorized generic during Glenmark/Par's 180-day exclusivity period, taking approximately 50% of Glenmark's generic sales and substantially lowering the price that drug purchasers paid for generic Zetia. Absent the no-AG promise, Glenmark/Par would not have agreed to delay its launch until December 12, 2016, and instead would have entered the market much sooner than it did, as early as December 6, 2011. Additional generics would have entered the market six months later and further driven down prices.

268. The settlement with Glenmark and Par enabled Merck to continue to receive monopoly profits until December 12, 2016 and enabled Glenmark and Par to control the generic market for 180 days thereafter, with Glenmark and Par sharing in the monopoly profits that the reciprocal non-competition pact made possible. The reverse payment agreement not only delayed entry into the market of the Glenmark/Par product, it also created a bottleneck that blocked all other would-be generic Zetia competitors by postponing the start (and thus also the conclusion) of Glenmark/Par's 180-day first-filer exclusivity period. Once Glenmark/Par's 180-day exclusivity period expired on June 12, 2017, seven other companies launched their generic Zetia products. Absent defendants' unlawful agreement to delay entry until December 12, 2016, these or other generic manufacturers would have filed their ANDA applications earlier and would have

been ready, willing, and able to enter the market on whatever earlier date Glenmark/Par's 180-day exclusivity expired.

269. The Merck-Glenmark/Par Settlement Agreement was collusive and intended to maintain a monopoly and allocate the market. In accordance with the Glenmark/Par Distribution Agreement, Par distributed generic Zetia in the United States starting in December 2016 as contemplated by defendants' unlawful reverse payment agreement. And Glenmark refrained from any generic Zetia manufacture, sale, or distribution inconsistent with the conspiracy's agreements, including the December 12, 2016 launch date for generic Zetia and facilitation of Par's distribution of generic Zetia in the United States as contemplated by the unlawful U.S. Distribution and reverse payment agreements.

Q. The no-AG promise was a large reverse payment.

270. The no-AG payment to Glenmark/Par was large, estimated to be worth more than $800 million. It far exceeded any estimate of the litigation expenses Merck saved by settling the patent case with Glenmark/Par.[72]

271. The value of the reverse payment agreement to Merck, estimated to be almost $9 billion, was far greater even than the value to Glenmark/Par, because the years-long delay in generic entry protected Merck's monopoly sales volume and pricing over that time.

272. Merck's reverse payment to Glenmark/Par guaranteed two distinct periods of non-competition: (a) the period before generic competition, wherein Merck and Glenmark/Par allocated 100% of the market to Merck; and (b) the 180-day exclusivity period after

[72] One 2015 survey of the cost of patent litigation found that litigation expenses for a case such as the one between Merck and Glenmark/Par range from $3.7 million to $6.3 million. *AIPLA 2015 Report of the Economic Survey*, IPICS, http://www.patentinsuranceonline.com/wp-content/uploads/2016/02/AIPLA-2015-Report-of-the-Economic-Survey.pdf (last visited Jan. 11, 2018).

Glenmark/Par's entry, wherein Merck and Glenmark/Par allocated 100% of generic sales to Glenmark/Par. So drug purchasers were overcharged twice: before Glenmark/Par's entry, they were forced to pay overcharges for branded Zetia; and during Glenmark/Par's exclusivity period were forced to pay additional overcharges for branded Zetia and generic Zetia. And the unlawful agreement had the additional anticompetitive effect of delaying the entry of all of the other generic competitors.

273. The defendants have no procompetitive explanation or justification for the reverse payment agreement.

274. If not for the reverse payment settlement agreement between Merck and Glenmark, Glenmark could and would have entered the market much sooner than it did, as early as December 6, 2011, with immediate competition from a Merck authorized generic and full competition with other generics by approximately May 2012. Instead, Glenmark/Par did not release its generic until December 12, 2016, Merck never launched an authorized generic, and generic entry by other manufacturers could not occur until June 12, 2017.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE DIRECT PURCHASER PLAINTIFFS AND THE CLASS

275. Merck's U.S. sales of Zetia were approximately $1.3 billion in 2010, $1.4 billion in 2012, $1.5 billion in 2014, and $2.6 billion in 2016. These amounts represent billions of dollars more in sales than Merck would have achieved absent the defendants' unlawful scheme to impair generic competition. Generic Zetia products would have been priced at a fraction of the cost of brand Zetia, and would have quickly captured the vast majority of the market for ezetimibe.

276. Merck's and Glenmark/Par's unlawful agreement impaired and delayed the sale of generic Zetia in the United States and unlawfully enabled Merck to sell its branded Zetia at

artificially inflated prices, and then allowed Glenmark/Par to sell its generic Zetia at artificially inflated prices. But for Merck's unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Zetia, at a much earlier date.

277. Were it not for the defendants' anticompetitive conduct, the direct purchaser plaintiffs and other members of the class would have: (1) purchased lower-priced generic Zetia, instead of the higher-priced brand Zetia, during the period when Glenmark delayed its entry to the market; (2) paid a lower price for generic Zetia products during Glenmark's 180-day exclusivity period; and (3) paid lower prices for generic Zetia products, as a result of the entry of generics at an earlier date, sooner.

278. As a consequence, the direct purchaser plaintiffs and other members of the class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VII. MARKET POWER AND DEFINITION

279. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Zetia, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while patient (and in most cases his or her insurer) has the obligation to pay for the product.

280. Brand manufacturers, including Merck, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive

to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

281. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Zetia.

282. Before December 12, 2016, Merck had monopoly power in the market for Zetia because it had the power to exclude competition and/or raise or maintain the price of ezetimibe at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable. From December 12, 2016 to June 12, 2017, Merck and Glenmark/Par combined had substantial market power in the market for Zetia and its generic equivalent, because they had the power to exclude competition and/or raise or maintain the price of ezetimibe at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

283. Before December 12, 2016, a small but significant, non-transitory increase to the price of brand Zetia would not have caused a significant loss of sales. From December 12, 2016 forward, a small but significant, non-transitory increase in the price of generic Zetia would not have caused a significant loss of sales.

284. Brand Zetia does not exhibit significant, positive cross-elasticity of demand with respect to price with any other ezetimibe product or treatment for hypercholesterolemia other

than AB-rated generic versions of Zetia.

285. Brand Zetia is differentiated from all other ezetimibe products, and all other hypercholesterolemia treatments, other than the AB-rated generic versions of brand Zetia.

286. Merck (and, later, Merck and Glenmark/Par) needed to control only brand Zetia and its AB-rated generic equivalents, and no other products, in order to maintain the price of ezetimibe profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would render the defendants unable to profitably maintain their prices for Zetia without losing substantial sales.

287. During the 180-day exclusion period, Merck sold brand Zetia and Glenmark/Par sold generic Zetia at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, Merck and Glenmark/Par enjoyed high profit margins.

288. The defendants had, and exercised, the power to exclude generic competition to brand Zetia.

289. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Zetia from the forces of price competition.

290. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the defendants' ability to control the price of Zetia and generic Zetia, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (a) generic Zetia would have entered the market at a much earlier date, at a substantial discount to brand Zetia, but for defendants' anticompetitive conduct; (b) Merck's gross margin on Zetia (including the costs of ongoing research/development and marketing) at all relevant times was very high; and (c) Merck never lowered the price of Zetia to the competitive level in response to the pricing of other brand or

generic drugs other than the AB-rated generic Zetia.

291. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiff alleges that the relevant antitrust market is the market for Zetia and its AB-rated generic equivalents.

292. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

293. Merck's market share in the relevant market was 100% until December 12, 2016, after which Merck and Glenmark/Par, collectively, had 100% market share in the relevant market until June of 2017, when Teva, Mylan, Sandoz, Amneal, Apotex, Ohm Laboratories/Sun Pharmaceuticals, Zydus, and Watson Laboratories all launched generic Zetia products.

VIII. MARKET EFFECTS

294. The defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The defendants designed a scheme to delay competition on the products' merits, to further Merck's anticompetitive purpose of forestalling generic competition against Zetia, in which Glenmark/Par cooperated in order to increase its own profits. The defendants carried out the scheme with the anticompetitive intent and effect of maintaining supra-competitive prices for ezetimibe tablets.

295. The defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Zetia, and later Glenmark/Par's generic Zetia, from competition. These actions allowed the defendants to maintain a monopoly and exclude competition in the market for Zetia and its AB-rated generic equivalents, to the detriment of the direct purchaser plaintiffs and all other members of the direct purchaser class.

296. The defendants' exclusionary conduct delayed generic competition and

unlawfully enabled Merck and Glenmark/Par to sell Zetia without further generic competition. Were it not for the defendants' illegal conduct, one or more additional generic versions of Zetia would have entered the market sooner, and Glenmark/Par's generic would have faced competition during its 180-day exclusivity period from a Merck authorized generic.

297. The defendants' illegal acts and conspiracy to delay generic competition for Zetia caused the direct purchaser plaintiffs and all members of the class to pay more than they would have paid for ezetimibe absent this illegal conduct.

298. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as the direct purchaser plaintiffs and members of the class, would have paid less for ezetimibe by (a) paying lower prices on their remaining brand purchases of Zetia, (b) substituting purchases of less-expensive generic Zetia for their purchases of more-expensive brand Zetia, and/or (c) purchasing generic Zetia at lower prices sooner.

299. Thus, the defendants' unlawful conduct deprived the direct purchaser plaintiffs and members of the class of the benefits from the competition that the antitrust laws are designed to ensure.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

300. During the relevant time period, the defendants manufactured, sold, and shipped Zetia and generic Zetia across state lines in an uninterrupted flow of interstate commerce.

301. During the relevant time period, the direct purchaser plaintiffs and members of the class purchased substantial amounts of Zetia and/or generic Zetia directly from the defendants. As a result of the defendants' illegal conduct, the plaintiff and the members of the class were compelled to pay, and did pay, artificially inflated prices for Zetia and generic Zetia.

302. During the relevant time period, the defendants used various devices to effectuate

the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

303. The defendants' conduct was within the flow of, and was intended to have and did have a substantial effect on, interstate commerce of the United States, including in this district.

304. During the class period, each defendant, or one or more of each defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme. The scheme in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

X. CLASS ACTION ALLEGATIONS

305. The direct purchaser plaintiffs bring this action on behalf of themselves and all others similarly situated under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure:

> All persons or entities in the United States and its territories that purchased Zetia or generic Zetia in any form directly from Merck, Glenmark/Par, or any other generic Zetia manufacturer (including, but not limited to, Teva, Sandoz, Amneal, Apotex, Aurobindo, Alkem Laboratories, Ohm Laboratories/Sun Pharmaceuticals, Zydus, and Watson) or any agents, predecessors, or successors thereof from December 6, 2011 until the effects of the defendants' conduct cease (the "class").

306. Excluded from the class are Merck, Glenmark, Par, and any of their officers, directors, management, employees, parents, subsidiaries, and affiliates.

307. Also excluded from the class are the government of the United States and all agencies thereof, and all state or local governments and all agencies thereof.

308. The class seeks damages for at least the four years preceding the date the complaint is filed.

309. Members of the direct purchaser class are so numerous and geographically

dispersed that joinder of all members is impracticable. The plaintiff believes that the class is numerous and widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The class is readily identifiable from information and records in the defendants' possession.

310. The direct purchaser plaintiffs' claims are typical of the claims of the members of the class. The direct purchaser plaintiffs and all members of the direct purchaser class were damaged by the same wrongful conduct of the defendants – i.e., as a result of the defendants' conduct, they paid artificially inflated prices for Zetia and any available AB-rated generic equivalents.

311. The direct purchaser plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of the direct purchaser plaintiffs are coincident with, and not antagonistic to, those of the other members of the class.

312. Counsel who represent the direct purchaser plaintiffs are experienced in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigations involving pharmaceutical products.

313. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

314. Questions of law and fact common to the class include:

a. Whether the defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. To the extent such justifications exist, whether there were less restrictive means of achieving them;

c. Whether direct proof of the defendants' monopoly power is available and, if so, whether it is sufficient to prove the defendants' monopoly power without the need to define the relevant market;

d. Whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

e. Whether the defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiff and the members of the class;

f. Whether defendants conspired to delay generic competition for Zetia;

g. Whether, pursuant to the reverse payment agreement, Merck's promise not to compete against Glenmark/Par's generic product constituted a payment;

h. Whether Merck's agreement with Glenmark/Par was necessary to yield some cognizable, non-pretextual procompetitive benefit;

i. Whether Merck's compensation to Glenmark/Par was large and unexplained;

j. Whether the reverse payment agreement created a bottleneck to further delay generic competition for Glenmark/Par;

k. Whether the reverse payment harmed competition;

l. Whether, before December 12, 2016, Merck possessed the ability to control prices and/or exclude competition for Zetia;

m. Whether, from December 12, 2016 through June 12, 2017, Merck, Glenmark, and Par possessed the ability to control prices and/or exclude competition for Zetia;

n. Whether the defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Zetia;

o. Determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic conduct caused, and;

p. The quantum of overcharges paid by the class in the aggregate.

315. Class action treatment is a superior method for the fair and efficient adjudication

of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

316. The direct purchaser plaintiffs know of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

XI. CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

317. A cause of action accrued for the direct purchaser plaintiffs each time defendants sold a product to direct purchaser plaintiffs at a supra-competitive price made possible by their anticompetitive conduct. And each sale by defendants of a product at a supra-competitive constituted another overt act in furtherance of their anticompetitive scheme. Accordingly, direct purchaser plaintiffs are entitled to recover all damages on all sales that defendants made to direct purchaser plaintiffs at supra-competitive prices within four years of the filing of this lawsuit.

318. Due to defendants' concealment of their unlawful conduct, however, direct purchaser plaintiffs and members of the class are entitled to recover damages reaching back even beyond four years of the filing of this complaint. That Merck paid Glenmark/Par in the form of a no-AG promise was not discoverable until after Glenmark/Par launched their generic ezetimibe in December 2016. At that time, Merck did not launch an authorized generic then, or after six months, or ever. Merck and Glenmark had earlier disclosed only cursory information about the existence of the settlement. The direct purchaser plaintiffs and members of the class had no knowledge of the defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years

before the filing of this complaint.

319. This is true because of the nature of the defendants' scheme was self-concealing and because the defendants employed deceptive tactics and techniques of secrecy to avoid detection of, and to conceal, their contract, combination, conspiracy and scheme.

320. The defendants and co-conspirators wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from plaintiff and members of the class by, among other things:

a. Concealing the fact of Merck's agreement not to launch a competing authorized generic Zetia product in exchange for Glenmark and Par's agreement not to market their competing generic product until December 12, 2016;

b. Concealing the fact that the purpose of the no-AG agreement was to provide compensation to Glenmark and Par in connection with the settlement of the patent litigation and the December 2016 entry date for Glenmark's generic product; and

c. Filing documents with the United States Securities and Exchange Commission that failed to disclose the existence or nature of the payments made.

321. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by the defendants, the direct purchaser plaintiffs and members of the class had no knowledge of the scheme and conspiracy more than four years before the filing of this complaint; nor did they have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

322. The direct purchaser plaintiffs and members of the class also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of the direct purchaser plaintiffs and members of the class would not have uncovered those facts more than four years before the filing of this complaint.

323. As a result of the defendants' fraudulent concealment, all applicable statutes of limitations affecting the plaintiff's and class members' claims have been tolled.

XII. CLAIMS FOR RELIEF

COUNT ONE – VIOLATION OF 15 U.S.C. § 1 (AGAINST MERCK, GLENMARK, AND PAR)

324. The direct purchaser plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

325. Merck, Glenmark, and Par violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for Zetia and its generic equivalents.

326. Direct purchasers have been injured in their business or property by the violation of 15 U.S.C. § 1. The direct purchasers' injury consists of having paid higher prices for its ezetimibe requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct unlawful. FWK, as an assignee of direct purchaser Frank W. Kerr Co., RDC, as a direct purchaser, and Cesar Castillo, Inc., as a direct purchaser, are the proper entities to bring a case concerning this conduct.

327. From the launch of brand Zetia in 2002 through December 12, 2016, Merck possessed monopoly power in the relevant market – i.e., the market for sales of ezetimibe in the United States. But for the defendants' wrongful conduct, as alleged herein, Merck should have lost its monopoly power in the relevant market as early as December 6, 2011 and in any event well before December 12, 2016.

328. On or about May 10, 2010, Merck, Glenmark, and Par entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under

which Merck paid Glenmark substantial consideration in exchange for Glenmark/Par's agreement to delay bringing its generic version of Zetia to the market, the purpose and effect of which were to: (a) delay generic entry of Zetia in order to lengthen the period in which Merck's brand Zetia could monopolize the market and make supra-competitive profits; (b) keep an authorized generic off the market during Glenmark/Par's 180-day generic exclusivity period, thereby allowing Glenmark to monopolize the generic market for Zetia during that period, and allowing Glenmark to make supra-competitive profits; and (c) raise and maintain the prices that the direct purchaser plaintiffs and other members of the class would pay for Zetia at supra-competitive levels until at least June 12, 2017.

329. From December 12, 2016 through June 12, 2017, Merck shared its monopoly power with Glenmark and Par, and the three companies jointly maintained an illegal monopoly throughout that time.

330. The May 2010 reverse payment agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

331. Merck, Glenmark, and Par are liable for this reverse payment agreement under a "rule of reason" standard under the antitrust laws.

332. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

333. As a direct and proximate result of Merck's, Glenmark's, and Par's anticompetitive conduct, including the reverse payment, the direct purchaser plaintiffs were harmed.

COUNT TWO – VIOLATION OF 15 U.S.C. § 2
(AGAINST MERCK, GLENMARK, AND PAR)

334. The direct purchaser plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

335. Merck, Glenmark, and Par entered into a conspiracy to monopolize in violation of 15 U.S.C. § 2 by entering into the reverse payment agreement.

336. Direct purchasers have been injured in their business or property by the violation of 15 U.S.C. § 2. Such injury consists of having paid higher prices for their ezetimibe requirements than they would have paid in the absence of those violations. Such injury is of the type antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct unlawful. FWK, RDC, and Cesar Castillo, Inc. are the proper entities to bring a case concerning this conduct.

XIII. DEMAND FOR JUDGMENT

337. WHEREFORE, the direct purchaser plaintiffs, on behalf of themselves and the proposed class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the class, and declare the direct purchaser plaintiffs as the representatives of the class;

b. Enter joint and several judgments against the defendants and in favor of the direct purchaser plaintiffs and the class;

c. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

d. Award the direct purchaser plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIV. JURY DEMAND

338. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the direct purchaser plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: June 27, 2019

Respectfully submitted,

/s/ William H. Monroe, Jr.
William H. Monroe, Jr. (VSB No. 27441)
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CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to all counsel of record who have made a formal appearance.

Dated: June 27, 2019

/s/William H. Monroe, Jr.
William H. Monroe, Jr.